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(54) **ACCOMMODATING INTRAOCULAR LENS**

- (71) Applicant: **LensGen, Inc.**, Irvine, CA (US)
- (72) Inventors: **Thomas Silvestrini**, Alamo, CA (US);
Ramgopal Rao, Irvine, CA (US)
- (73) Assignee: **LensGen, Inc.**, Irvine, CA (US)
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- (52) **U.S. Cl.**
CPC **A61F 2/1613** (2013.01); **A61F 2/16** (2013.01); **A61F 2/1616** (2013.01); **A61F 2/1629** (2013.01); **A61F 2/1635** (2013.01); **A61F 2/1648** (2013.01); **A61F 2002/169** (2015.04); **A61F 2250/0003** (2013.01); **A61F 2250/0004** (2013.01); **A61F 2250/0008** (2013.01)

- (58) **Field of Classification Search**
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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,373,218 A	2/1983	Schachar
4,512,040 A	4/1985	McClure
4,585,457 A	4/1986	Kalb
4,720,286 A	1/1988	Bailey et al.
4,731,078 A	3/1988	Stay et al.
4,822,360 A	4/1989	Deacon

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0766540 B1	8/1999
WO	WO2009015226 A3	1/2009

(Continued)

Primary Examiner — David Isabella

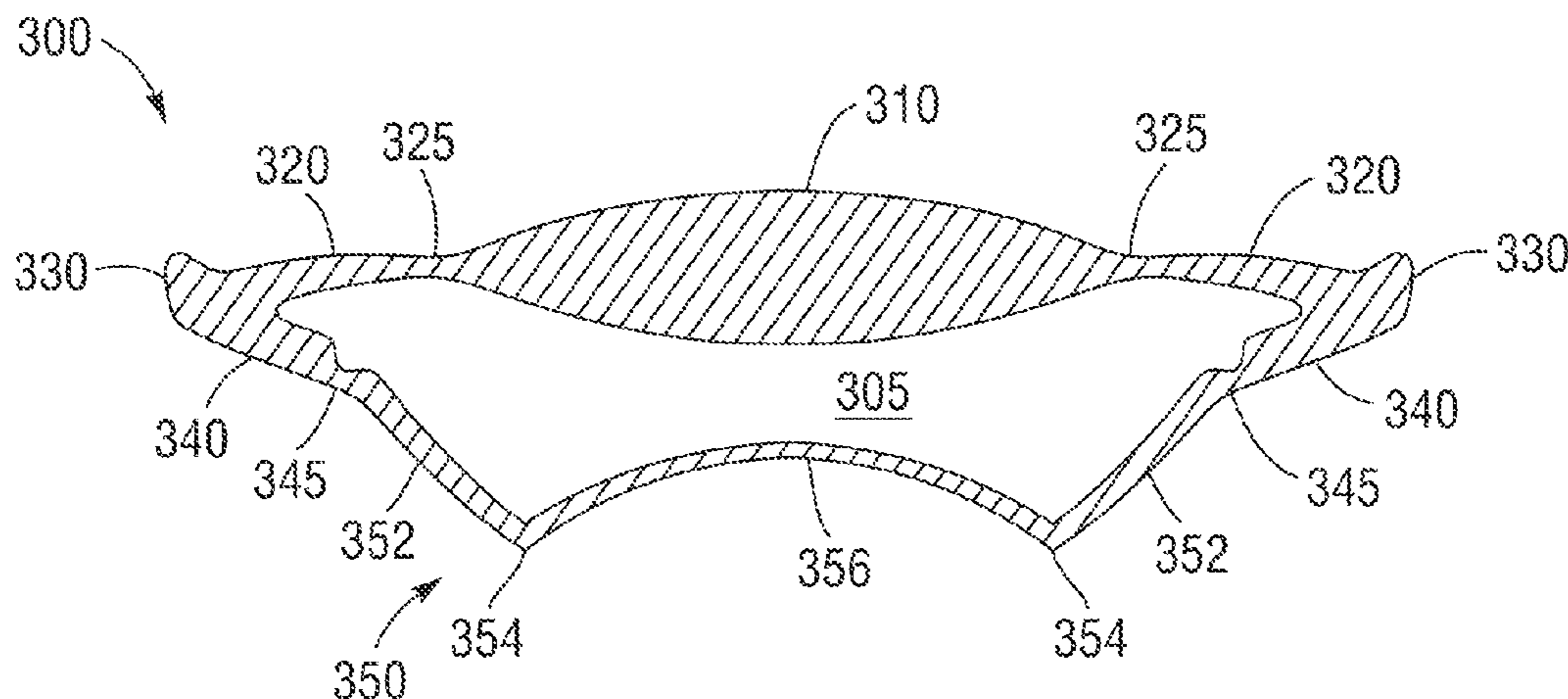
Assistant Examiner — Christine Nelson

(74) *Attorney, Agent, or Firm* — Sheppard Mullin Richter & Hampton LLP

(57) **ABSTRACT**

An accommodating intraocular lens (IOL) comprises an anterior lens, a posterior surface and an articulating member joining the anterior lens and the posterior surface to define an enclosed cavity. The articulating member comprises anterior and posterior arms coupling the anterior lens and the posterior surface, respectively. The articulating member further comprising a peripheral portion. A posterior flex region is disposed about the posterior arm and at a distance from the peripheral portion. The posterior flex region permits the flexible posterior surface to articulate relative to the posterior arm, to decrease the radius of curvature of the posterior surface as the peripheral portions on opposing sides of the IOL move toward one another in a first state and to increase the radius of curvature of the posterior surface as the peripheral portions on opposite sides of the IOL move away from one another in a second state.

18 Claims, 14 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,842,601	A	6/1989	Smith	2004/0181279	A1	9/2004	Nun
4,888,012	A	12/1989	Horn et al.	2005/0071002	A1	3/2005	Glazier
4,892,543	A	1/1990	Turley	2005/0107873	A1	5/2005	Zhou
4,932,966	A	7/1990	Christie et al.	2005/0119740	A1	6/2005	Esch et al.
5,035,710	A	7/1991	Nakada et al.	2005/0137703	A1	6/2005	Chen
5,091,121	A	2/1992	Nakada et al.	2005/0251253	A1	11/2005	Gross
5,275,623	A	1/1994	Sarfarazi	2005/0251254	A1	11/2005	Brady et al.
5,443,506	A	8/1995	Garabet	2006/0041307	A1	2/2006	Esch et al.
5,489,302	A	2/1996	Skottun	2006/0047339	A1	3/2006	Brown
5,607,472	A	3/1997	Thompson	2006/0074487	A1	4/2006	Gilg
6,117,171	A	9/2000	Skottun	2006/0100701	A1	5/2006	Esch et al.
6,730,123	B1	5/2004	Klopotek	2006/0155372	A1	7/2006	Coroneo
6,855,164	B2	2/2005	Glazier	2006/0212116	A1	9/2006	Woods
6,930,838	B2	8/2005	Schachar	2007/0010880	A1	1/2007	Esch
7,063,723	B2	6/2006	Ran	2007/0021831	A1	1/2007	Clarke
7,122,053	B2	10/2006	Esch	2007/0088433	A1	4/2007	Esch et al.
7,217,288	B2	5/2007	Esch et al.	2007/0100445	A1	5/2007	Shadduck
7,220,279	B2	5/2007	Nun	2007/0106377	A1	5/2007	Smith et al.
7,229,475	B2	6/2007	Glazier	2007/0118216	A1	5/2007	Pynson
7,247,168	B2	7/2007	Esch et al.	2007/0129798	A1	6/2007	Chawdhary
7,261,737	B2	8/2007	Esch et al.	2007/0129799	A1	6/2007	Schedler
7,416,562	B2	8/2008	Gross	2007/0129800	A1	6/2007	Cumming
7,438,723	B2	10/2008	Esch	2007/0129801	A1	6/2007	Cumming
7,453,646	B2	11/2008	Lo	2007/0185574	A1	8/2007	Nun
7,485,144	B2	2/2009	Esch	2007/0203578	A1	8/2007	Scholl et al.
7,637,947	B2	12/2009	Smith et al.	2007/0213817	A1	9/2007	Esch et al.
7,675,686	B2	3/2010	Lo et al.	2007/0244561	A1	10/2007	Nun
7,753,953	B1	7/2010	Yee	2007/0260310	A1	11/2007	Richardson
7,776,088	B2	8/2010	Shadduck	2008/0004699	A1	1/2008	Nun
7,815,678	B2	10/2010	Nun	2008/0015689	A1	1/2008	Esch et al.
7,842,087	B2	11/2010	Nun	2008/0033547	A1	2/2008	Chang et al.
7,854,764	B2	12/2010	Nun	2008/0046074	A1	2/2008	Smith et al.
7,857,850	B2	12/2010	Mentak et al.	2008/0046075	A1	2/2008	Esch et al.
7,981,155	B2	7/2011	Cumming	2008/0154364	A1	6/2008	Richardson et al.
7,985,253	B2	7/2011	Cumming	2008/0188930	A1	8/2008	Mentak et al.
7,998,199	B2	8/2011	Nun	2008/0269887	A1	10/2008	Cumming
8,018,658	B2	9/2011	Lo	2008/0300680	A1	12/2008	Nun
8,034,106	B2	10/2011	Mentak et al.	2008/0306588	A1	12/2008	Smiley et al.
8,034,107	B2	10/2011	Stenger	2008/0306589	A1	12/2008	Donitzky et al.
8,038,711	B2	10/2011	Clarke	2009/0005865	A1	1/2009	Smiley et al.
8,048,155	B2	11/2011	Shadduck	2009/0027661	A1	1/2009	Choi et al.
8,052,752	B2	11/2011	Woods et al.	2009/0149952	A1	6/2009	Shadduck
8,070,806	B2	12/2011	Khoury	2009/0204210	A1	8/2009	Pynson
8,158,712	B2	4/2012	Your	2009/0264998	A1	10/2009	Mentak et al.
8,197,541	B2	6/2012	Schedler	2009/0292355	A1	11/2009	Boyd et al.
8,216,306	B2	7/2012	Coroneo	2009/0319040	A1	12/2009	Khoury
8,254,034	B1	8/2012	Shields et al.	2010/0030332	A1	2/2010	Schedler
8,273,123	B2	9/2012	Nun	2010/0094412	A1	4/2010	Wensrich
8,314,927	B2	11/2012	Choi et al.	2010/0121444	A1	5/2010	Nun
8,320,049	B2	11/2012	Huang et al.	2010/0131058	A1	5/2010	Shadduck
8,328,869	B2	12/2012	Smiley et al.	2010/0179653	A1	7/2010	Argento et al.
8,361,145	B2	1/2013	Scholl et al.	2010/0211169	A1	8/2010	Stanley et al.
8,398,709	B2	3/2013	Nun	2010/0228344	A1	9/2010	Shadduck
8,414,646	B2	4/2013	De Juan, Jr. et al.	2010/0288346	A1	9/2010	Esch
8,425,599	B2	4/2013	Shadduck	2010/0324672	A1	12/2010	Esch et al.
8,447,086	B2	5/2013	Hildebrand et al.	2010/0324674	A1	12/2010	Brown
8,454,688	B2	6/2013	Esch et al.	2011/0029074	A1	2/2011	Reisin et al.
8,475,529	B2	7/2013	Clarke	2011/0082544	A1	4/2011	Nun
8,545,556	B2	10/2013	Woods et al.	2011/0112636	A1	5/2011	Nun
8,585,758	B2	11/2013	Woods	2011/0118834	A1	5/2011	Lo et al.
8,657,878	B2	2/2014	Mentak et al.	2011/0160852	A1	6/2011	Mentak et al.
8,715,346	B2	5/2014	De Juan, Jr. et al.	2011/0224788	A1	9/2011	Webb
8,734,509	B2	5/2014	Mentak et al.	2011/0282442	A1	11/2011	Scholl et al.
8,814,934	B2	8/2014	Geraghty et al.	2011/0288638	A1	11/2011	Smiley et al.
8,834,565	B2	9/2014	Nun	2012/0035724	A1	2/2012	Clarke
8,900,298	B2	12/2014	Anvar et al.	2012/0071972	A1	3/2012	Zhao
2003/0093149	A1	5/2003	Glazier	2012/0078361	A1	3/2012	Shadduck
2003/0105522	A1	6/2003	Glazier	2012/0078364	A1	3/2012	Stenger
2003/0149480	A1	8/2003	Shadduck	2012/0150292	A1	6/2012	Mentak et al.
2004/0082993	A1	4/2004	Woods	2012/0290084	A1	11/2012	Coroneo
2004/0082994	A1	4/2004	Woods et al.	2012/0296423	A1	11/2012	Caffey
2004/0111153	A1	6/2004	Woods et al.	2012/0296424	A1*	11/2012	Betser A61F 2/1613 623/6.13
2004/0148023	A1	7/2004	Shu	2012/0310343	A1*	12/2012	Van Noy A61F 2/1635 623/6.39
2004/0162612	A1	8/2004	Portney et al.	2013/0006353	A1	1/2013	Betser et al.
2004/0169816	A1	9/2004	Esch	2013/0018461	A1	1/2013	Nun
				2013/0035760	A1	2/2013	Portney
				2013/0131794	A1	5/2013	Smiley et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2013/0150960 A1* 6/2013 DeBoer A61L 27/48
623/6.13
2013/0190867 A1 7/2013 Peyman
2013/0226295 A1 8/2013 De Juan, Jr. et al.
2013/0231741 A1 9/2013 Clarke
2013/0250239 A1 9/2013 Hildebrand et al.
2013/0268070 A1 10/2013 Esch et al.
2013/0317607 A1* 11/2013 DeBoer A61F 2/1635
623/6.13
2014/0012277 A1 1/2014 Matthews et al.
2014/0135918 A1 5/2014 De Juan, Jr. et al.
2014/0249625 A1 9/2014 Shaddock

FOREIGN PATENT DOCUMENTS

WO WO2011/137191 A1 11/2011
WO WO2013016804 A1 2/2013

* cited by examiner

FIG. 1

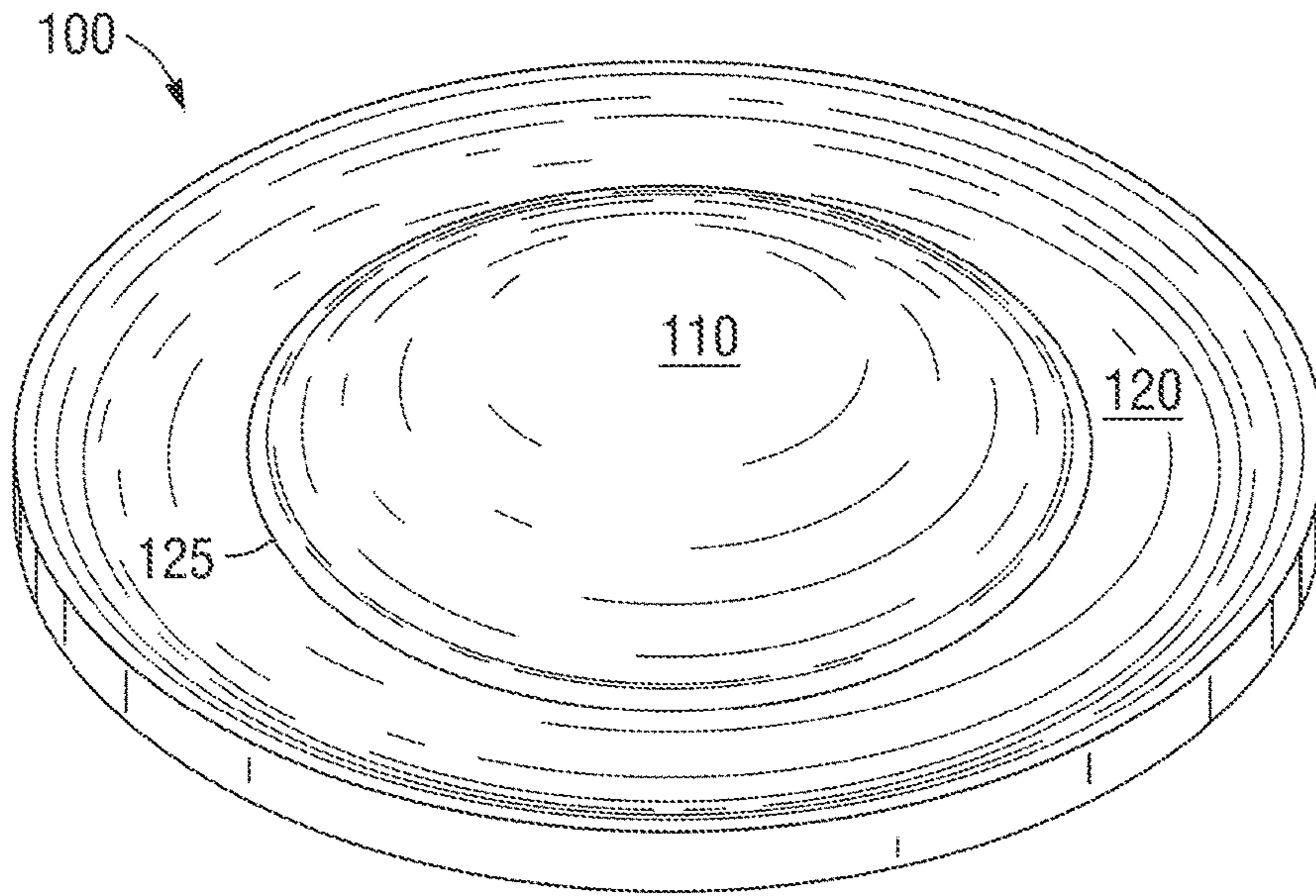


FIG. 2

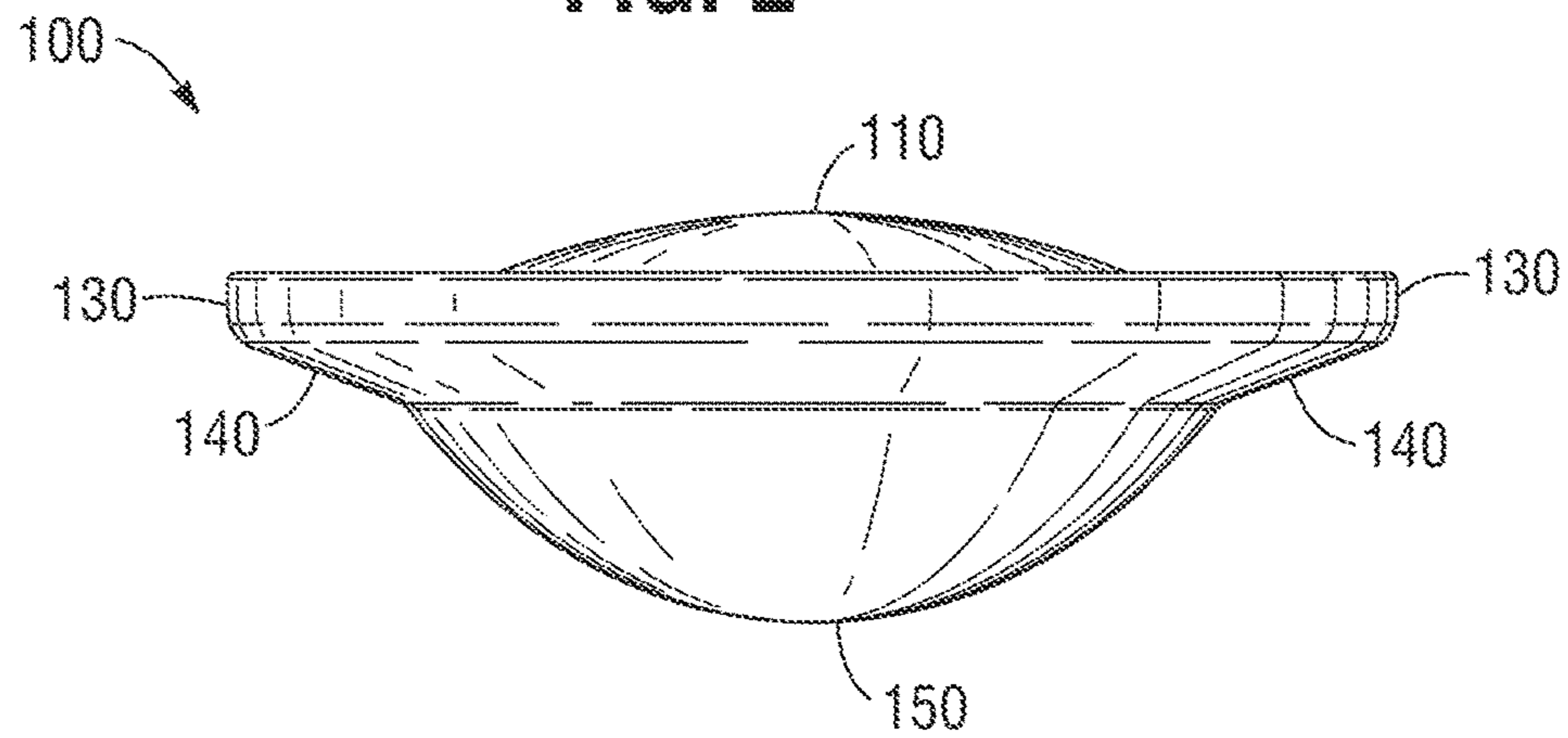


FIG. 3

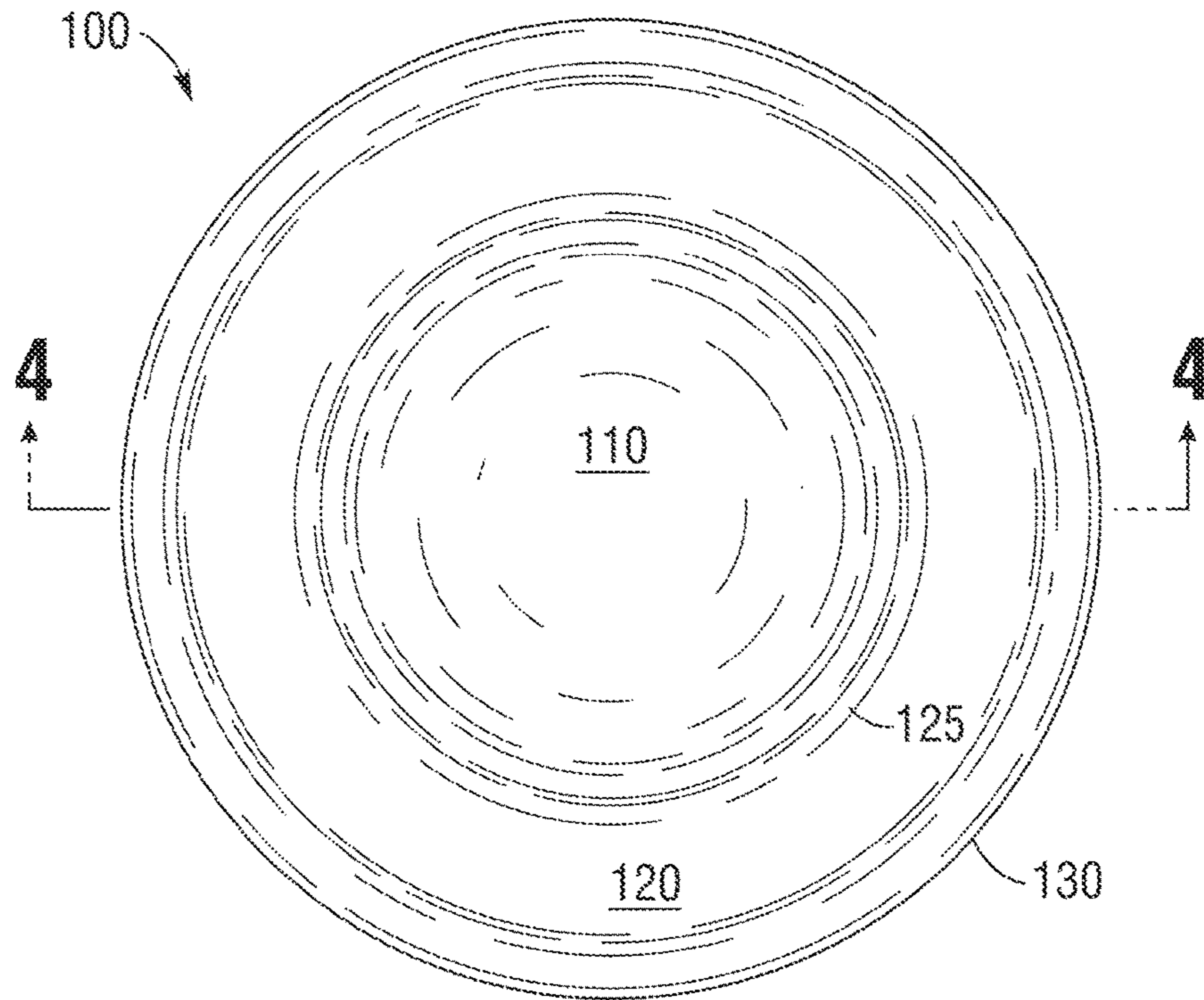


FIG. 4A

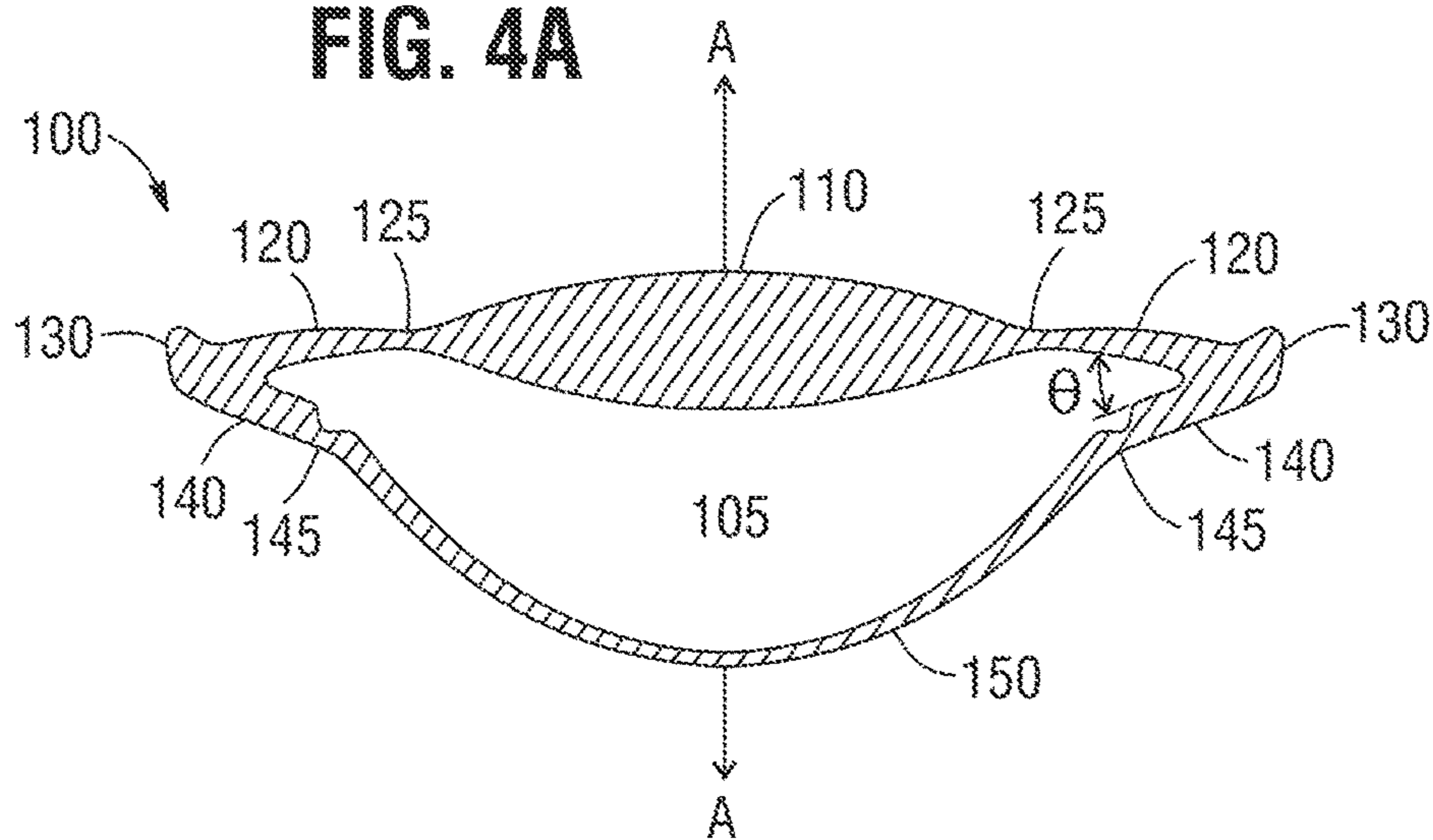


FIG. 4B

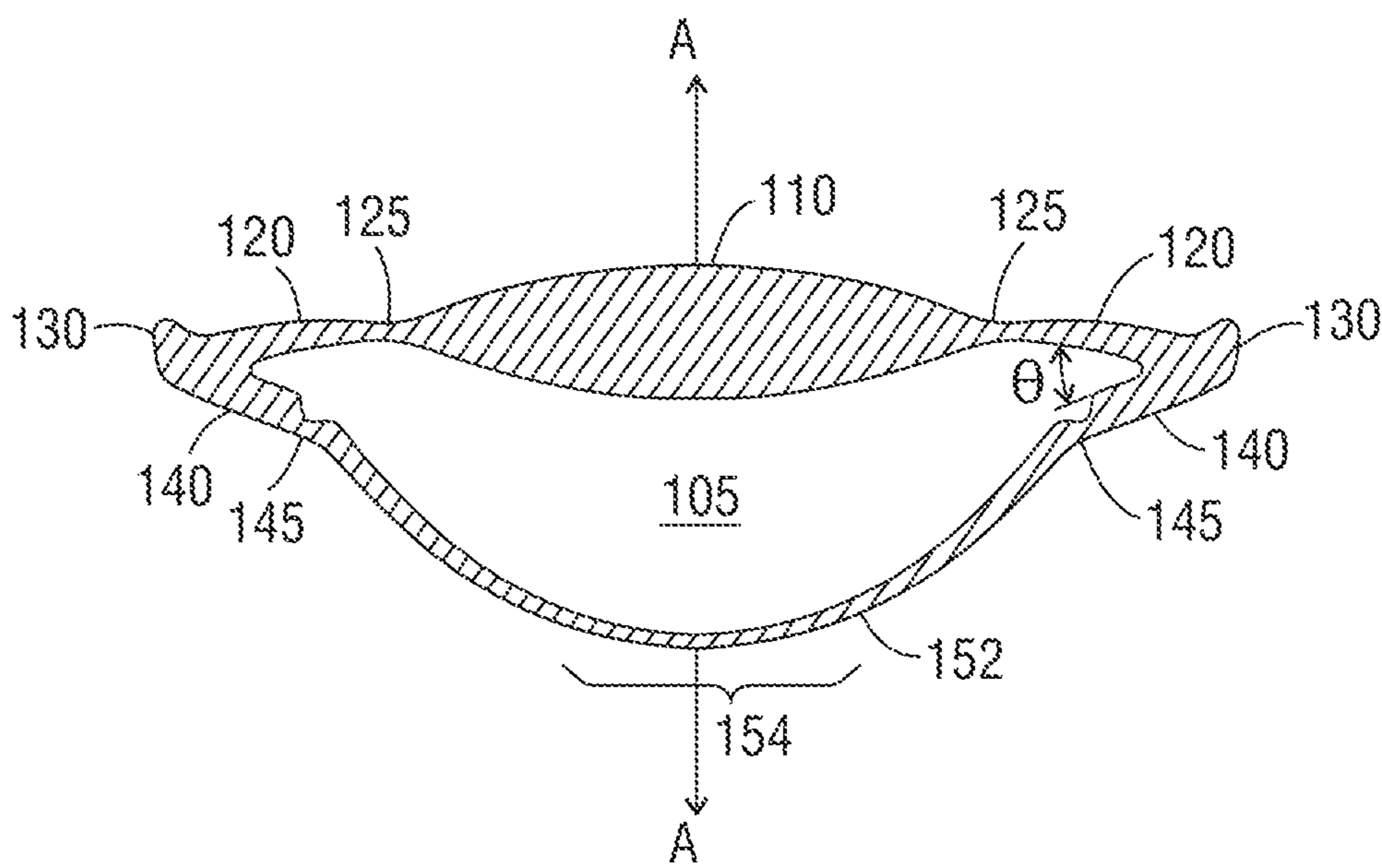


FIG. 4C

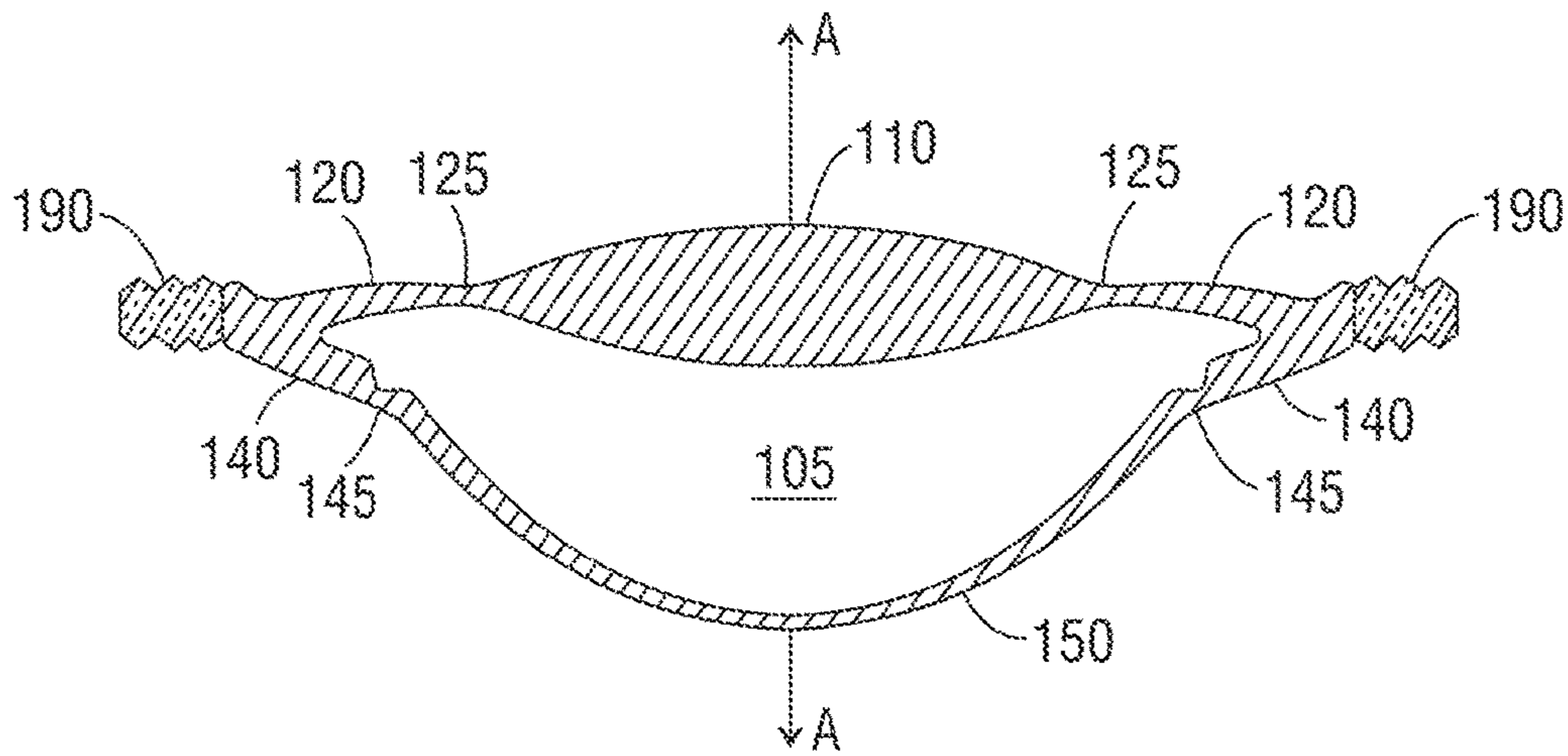


FIG. 5

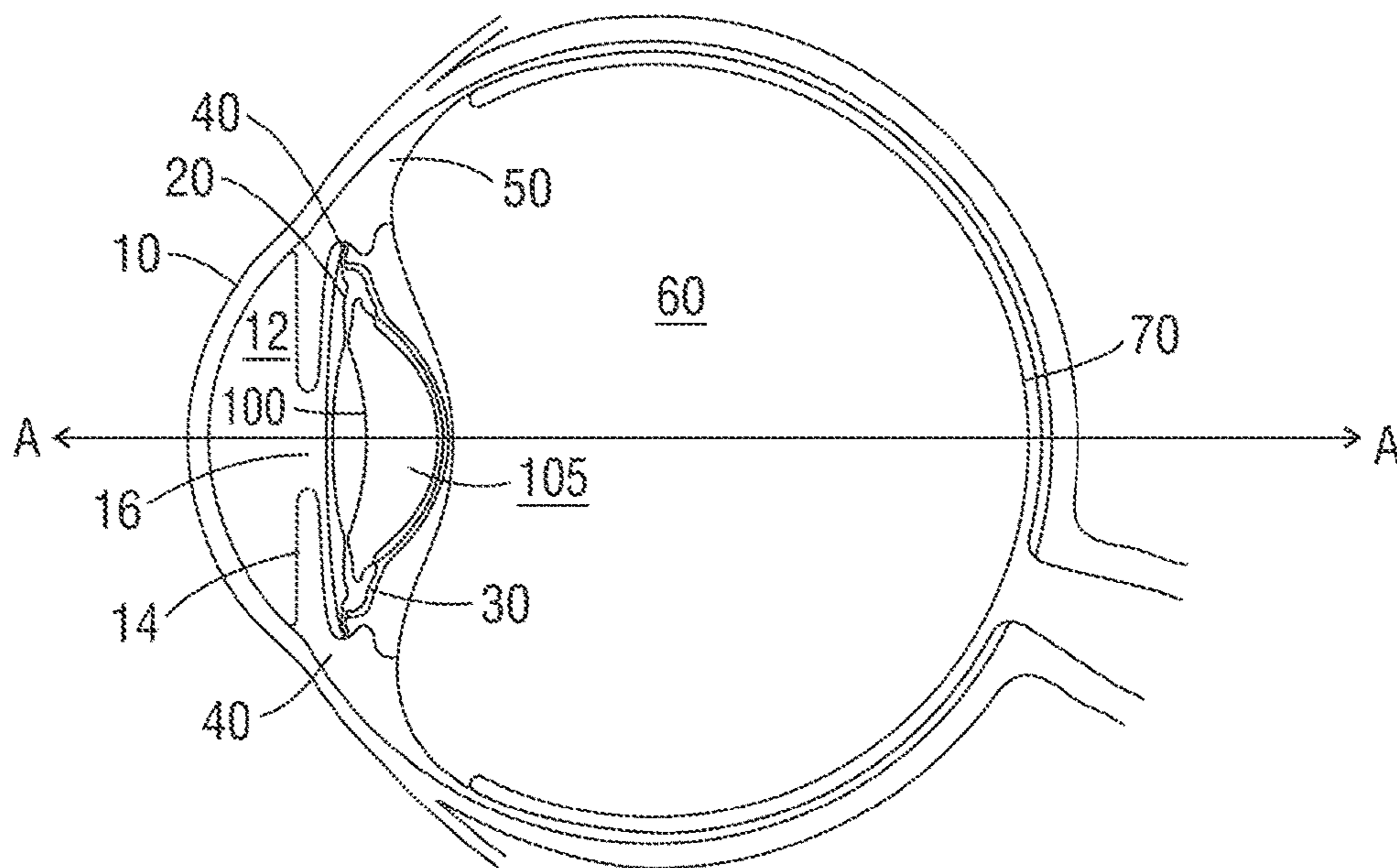


FIG. 6

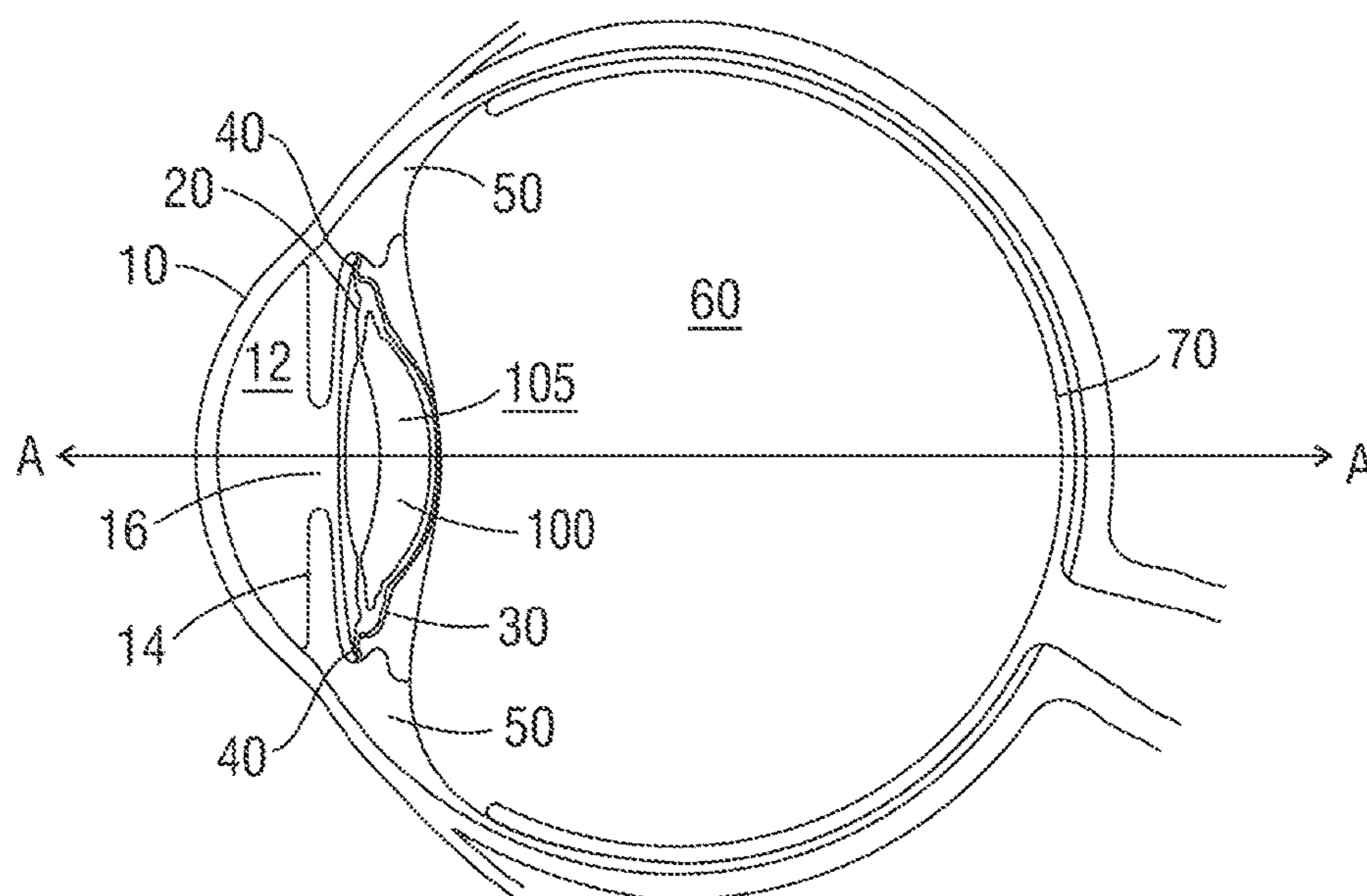


FIG. 7

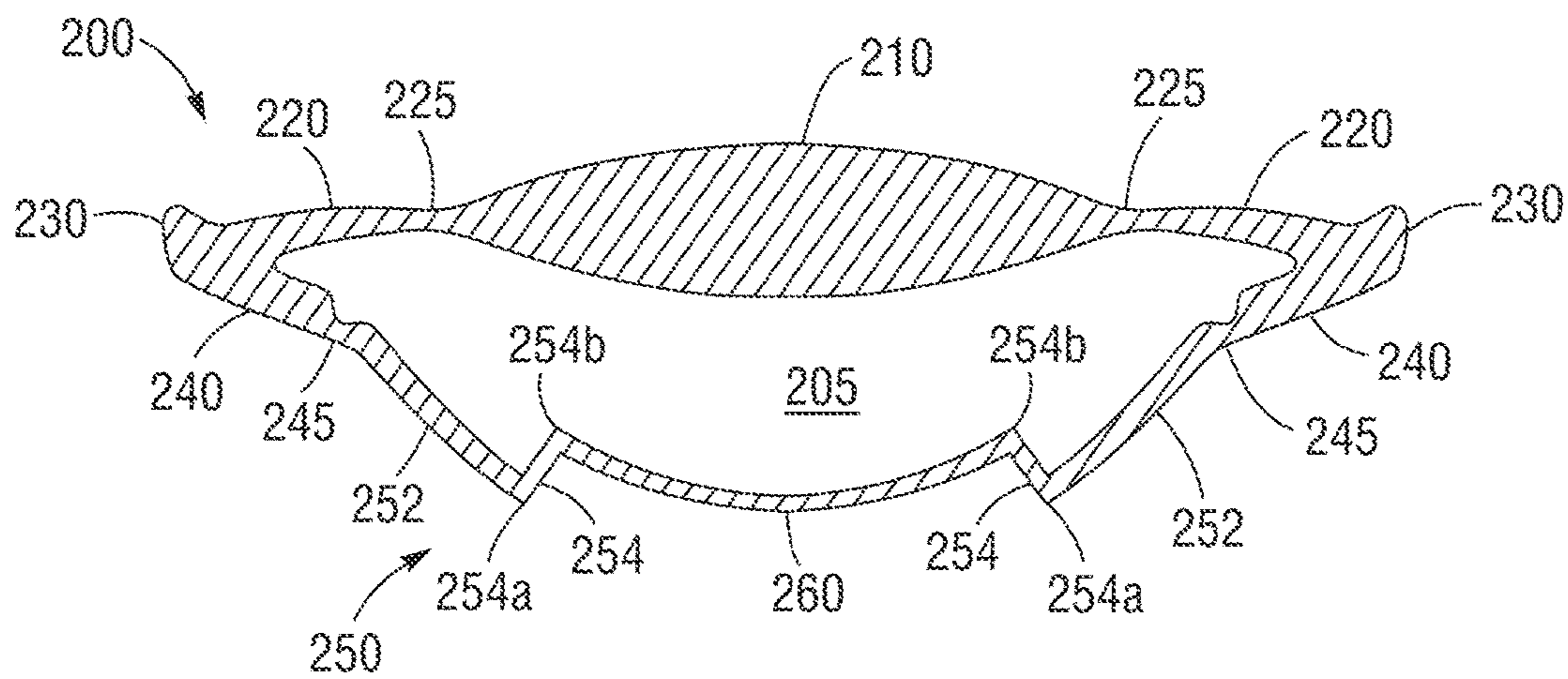


FIG. 8

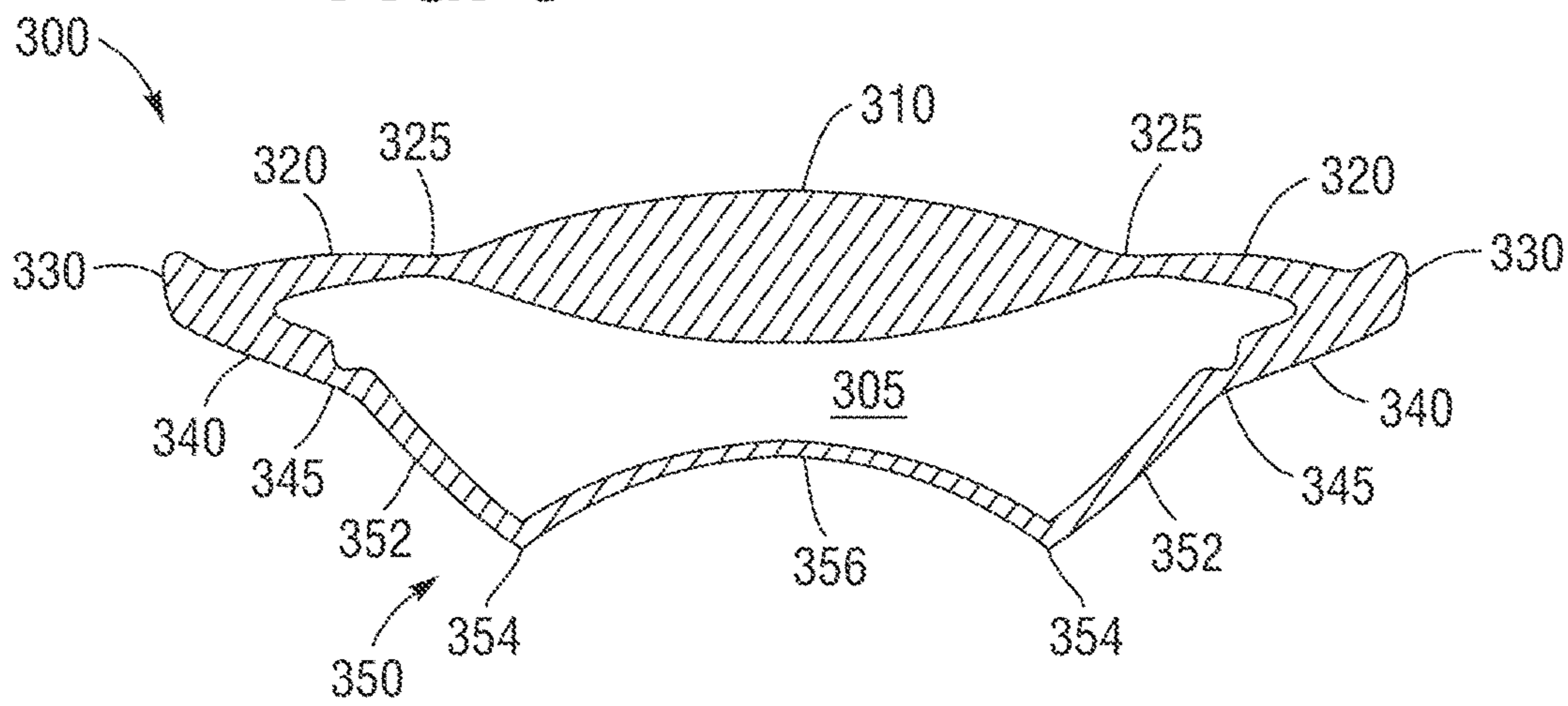


FIG. 9

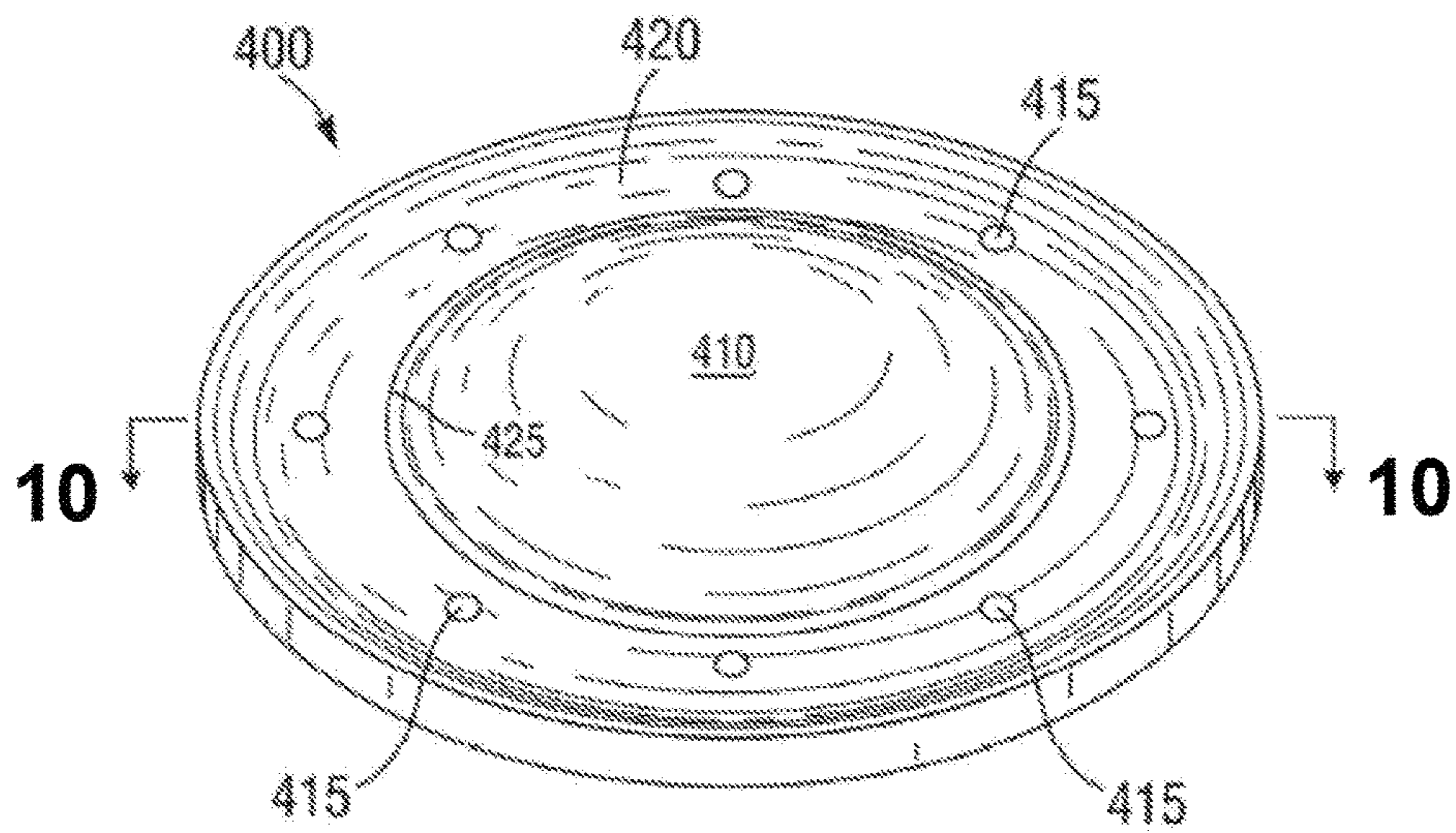


FIG. 10A

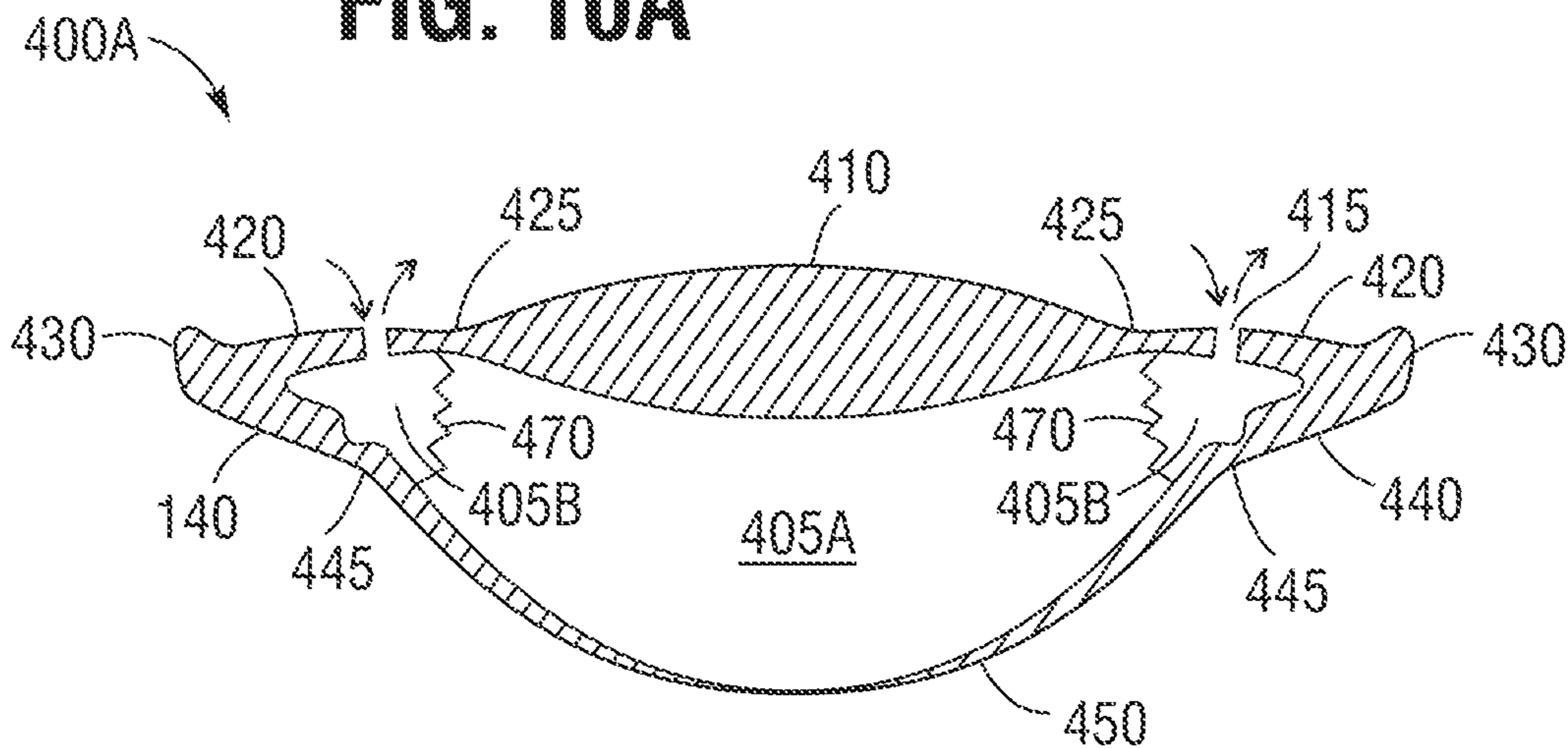


FIG. 10B

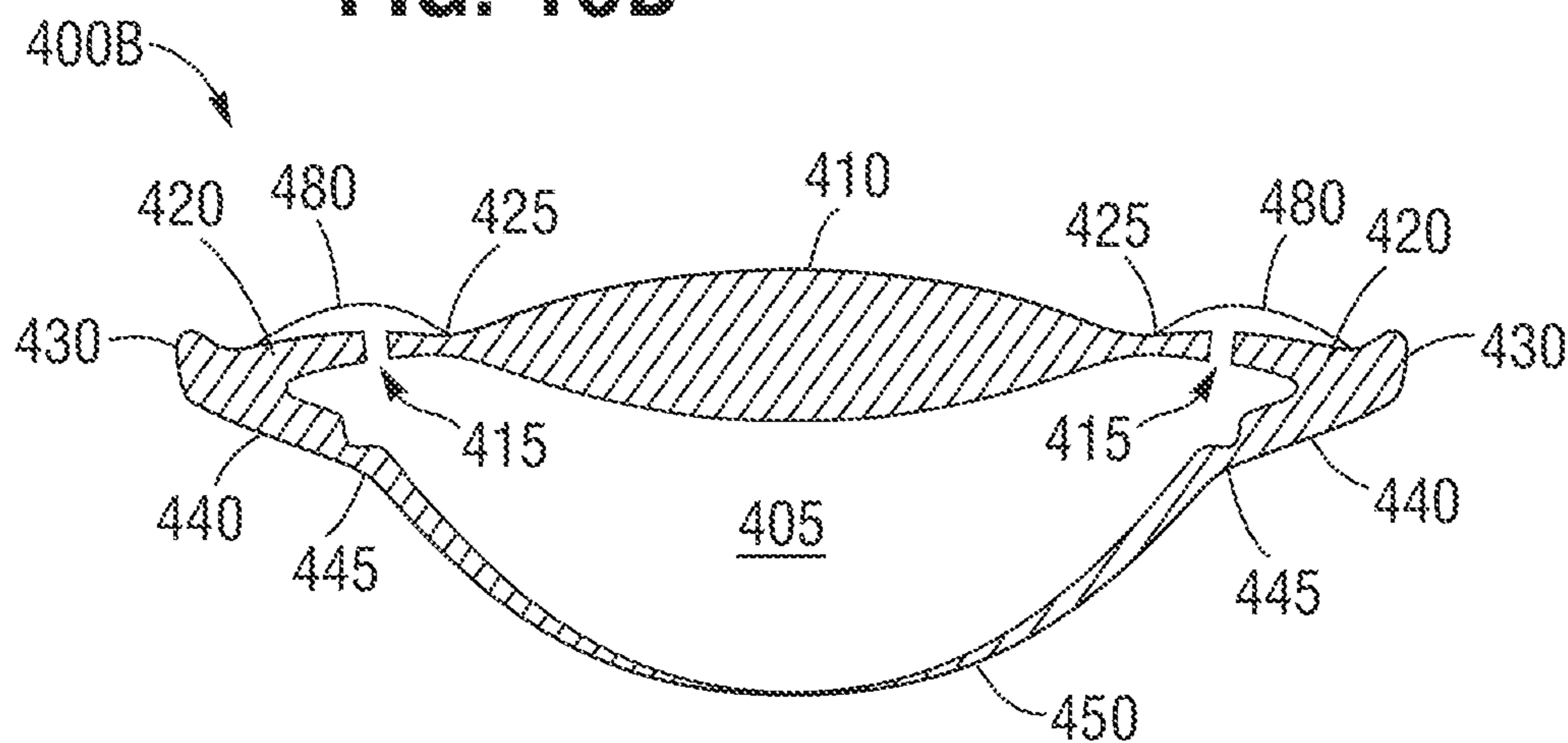
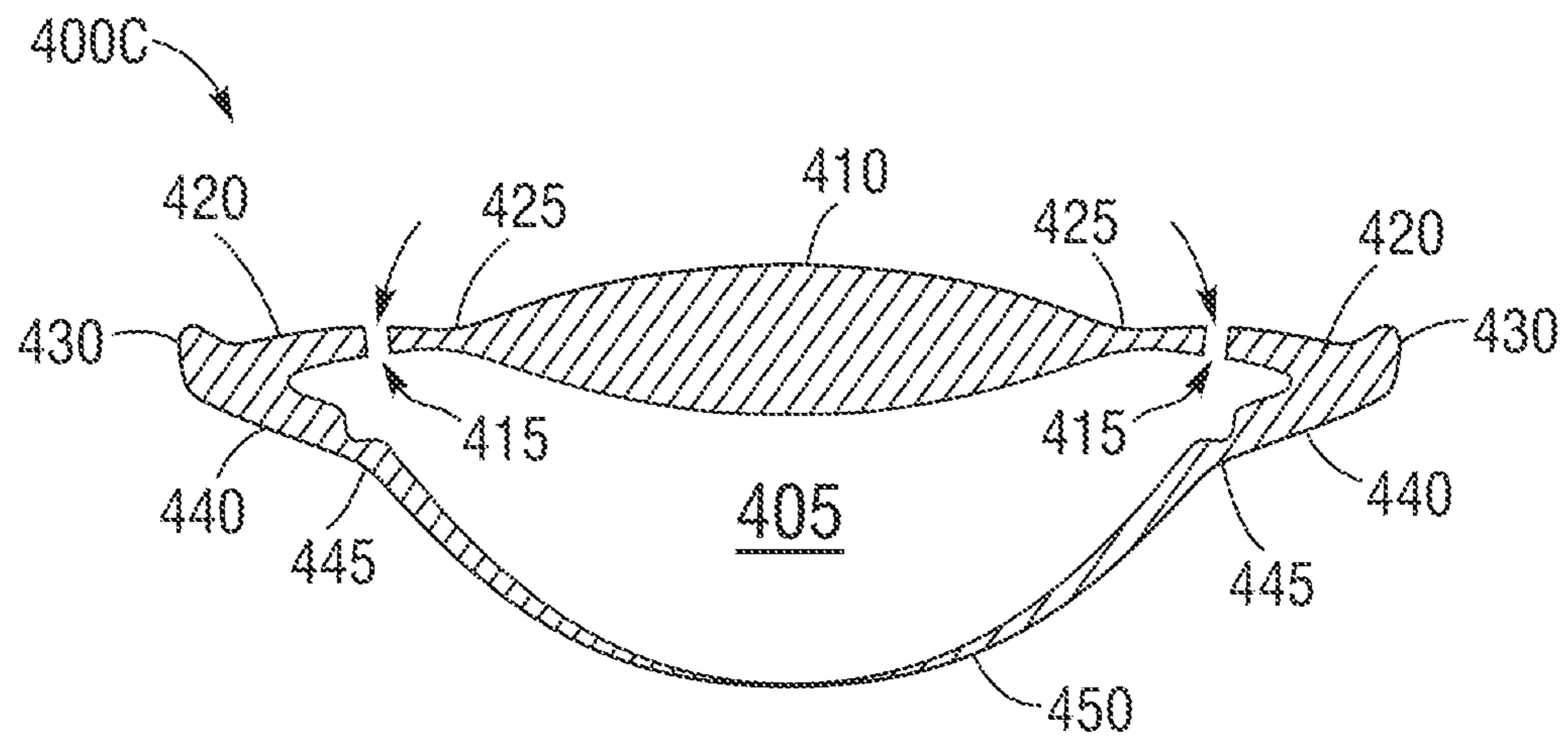


FIG. 10C



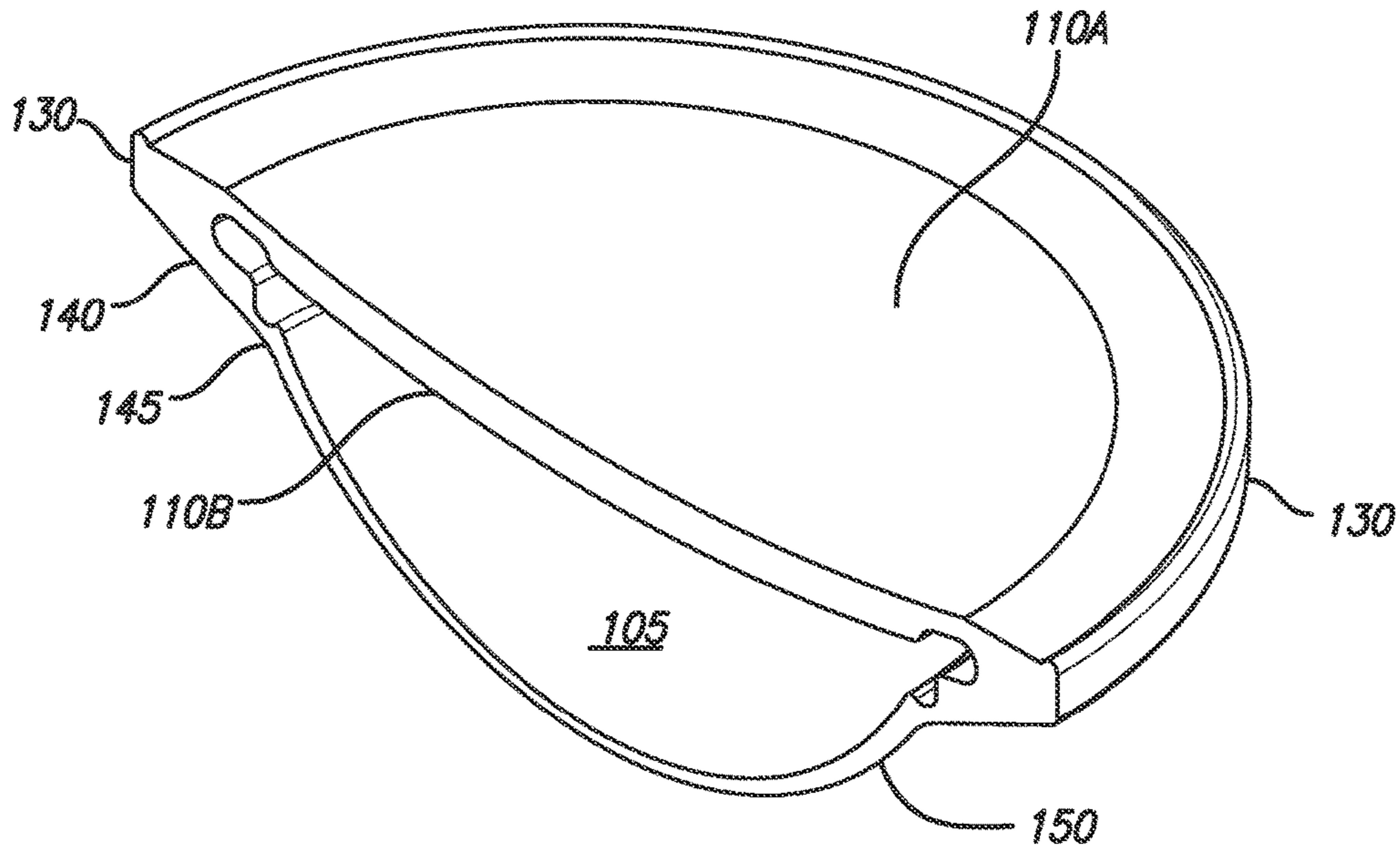


FIG. 11A

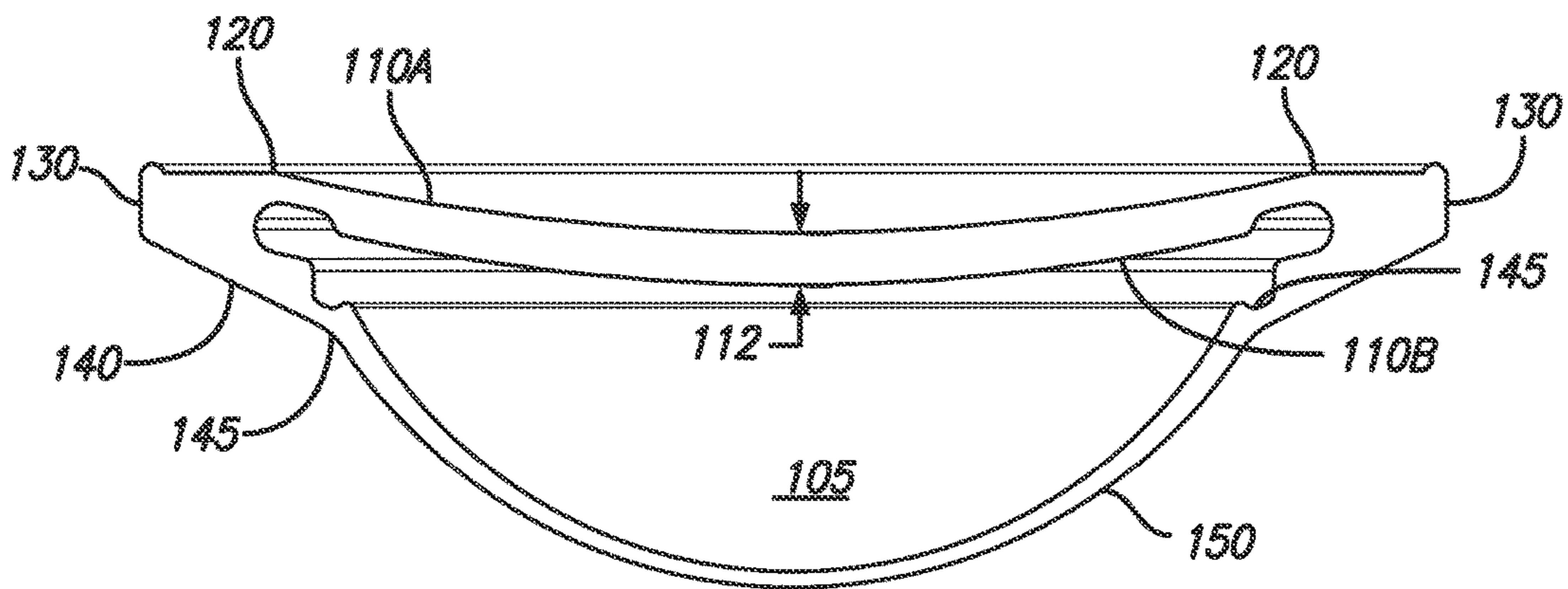


FIG. 11B

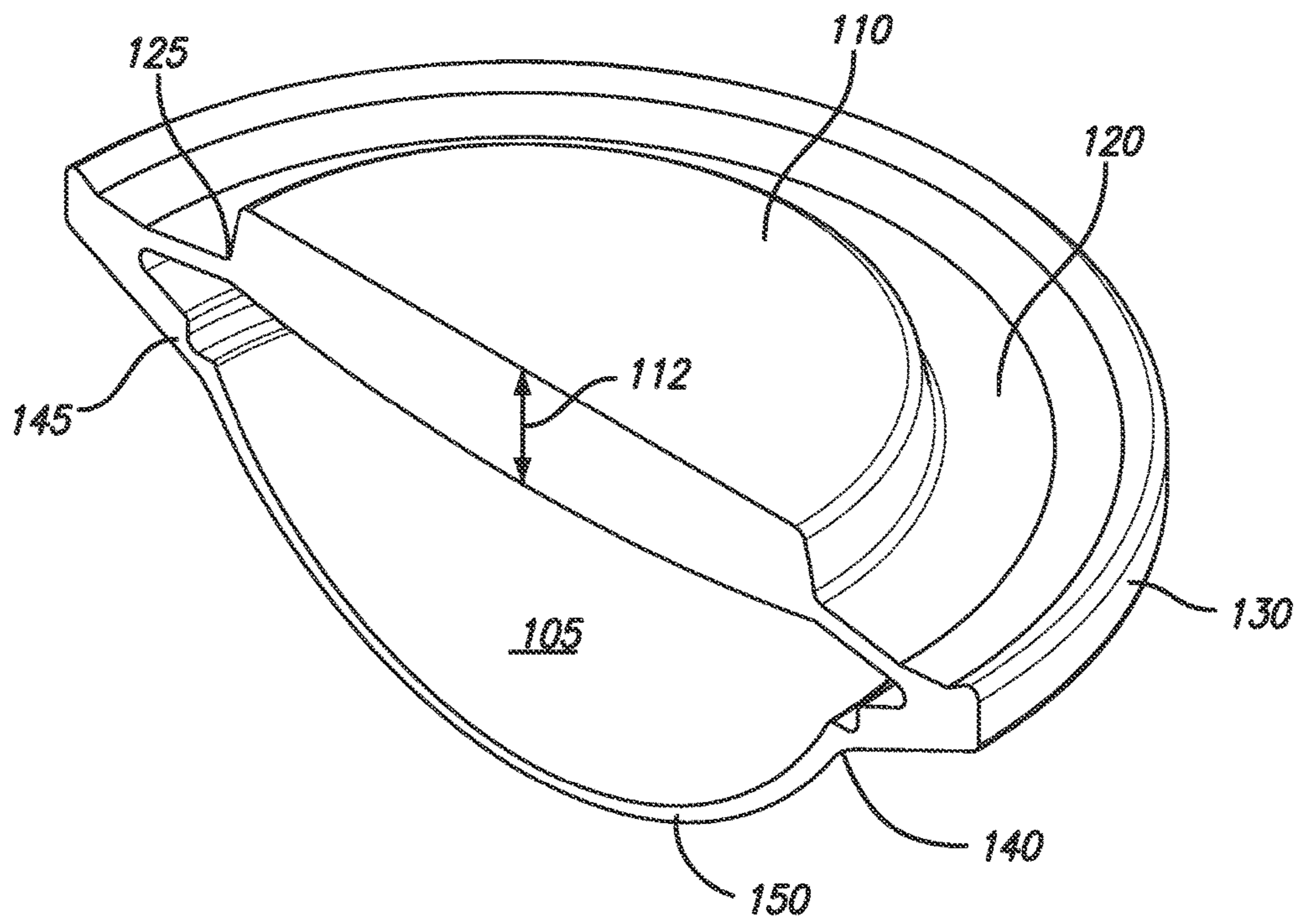


FIG. 12

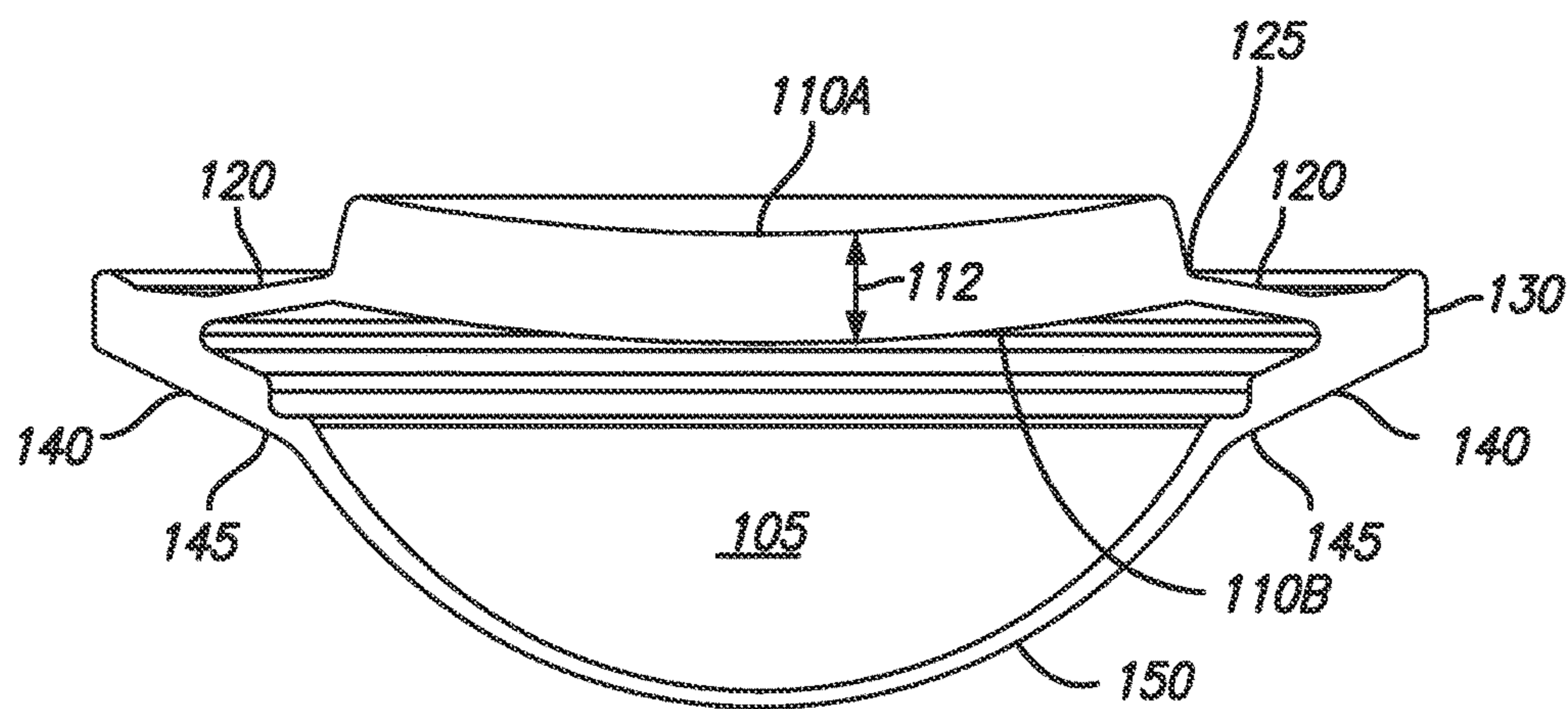


FIG. 13

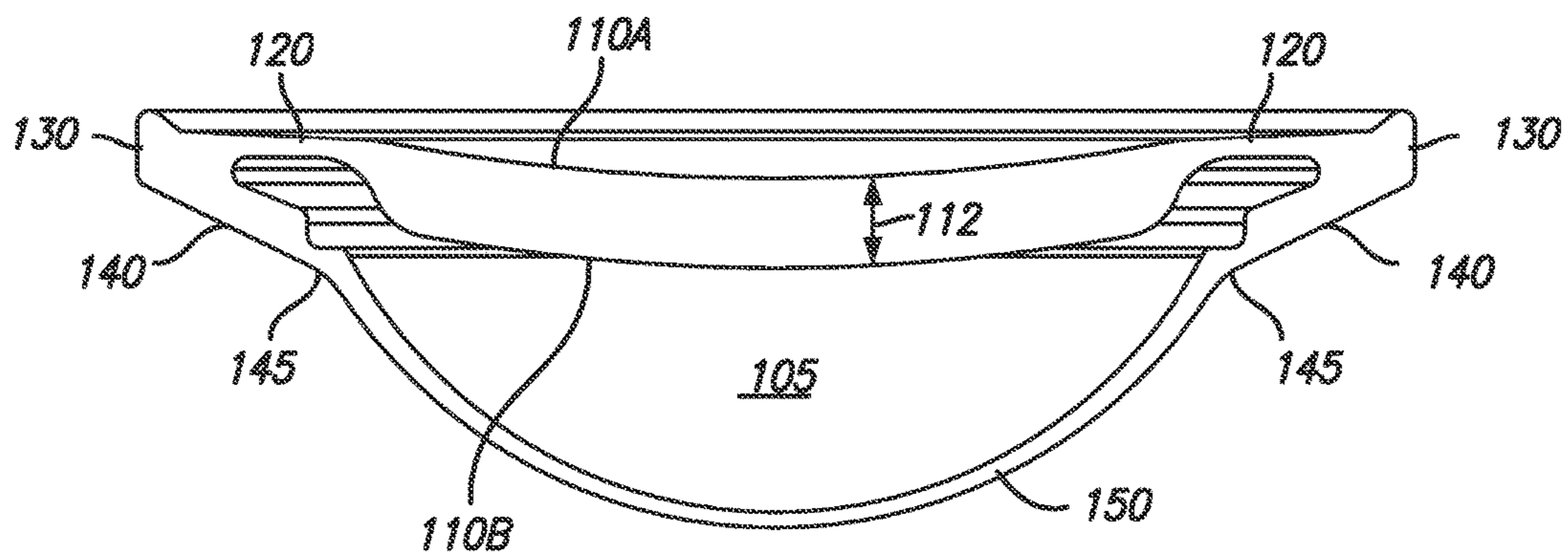


FIG. 14

ACCOMMODATING INTRAOCULAR LENS**CROSS-REFERENCE TO RELATED APPLICATION**

This application is a continuation of U.S. patent application Ser. No. 13/725,895, filed Dec. 21, 2012, the entire contents of which are incorporated herein by reference as if fully set forth herein.

FIELD OF THE INVENTION

The invention relates generally to an accommodating intraocular lens device and, more particularly, to an accommodating intraocular lens device configured for implantation in a lens capsule of a subject's eye.

BACKGROUND

Surgical procedures on the eye have been on the rise as technological advances permit for sophisticated interventions to address a wide variety of ophthalmic conditions. Patient acceptance has increased over the last twenty years as such procedures have proven to be generally safe and to produce results that significantly improve patient quality of life.

Cataract surgery remains one of the most common surgical procedures, with over 16 million cataract procedures being performed worldwide. It is expected that this number will continue to rise as average life expectancies continue to increase. Cataracts are typically treated by removing the crystalline lens from the eye and implanting an intraocular lens ("IOL") in its place. As conventional IOL devices are primarily focused for distance visions, they fail to correct for presbyopia and reading glasses are still required. Thus, while patients who undergo a standard IOL implantation no longer experience clouding from cataracts, they are unable to accommodate, or change focus from near to far, from far to near, and to distances in between.

Surgeries to correct refractive errors of the eye have also become extremely common, of which LASIK enjoys substantial popularity with over 700,000 procedures being performed per year. Given the high prevalence of refractive errors and the relative safety and effectiveness of this procedure, more and more people are expected to turn to LASIK or other surgical procedures over conventional eyeglasses or contact lens. Despite the success of LASIK in treating myopia, there remains an unmet need for an effective surgical intervention to correct for presbyopia, which cannot be treated by conventional LASIK procedures.

As nearly every cataract patient also suffers from presbyopia, there is convergence of market demands for the treatment of both these conditions. While there is a general acceptance among physicians and patients of having implantable intraocular lens in the treatment of cataracts, similar procedures to correct for presbyopia represent only 5% of the U.S. cataract market. There is therefore a need to address both ophthalmic cataracts and/or presbyopia in the growing aging population.

BRIEF SUMMARY

In one embodiment, an accommodating intraocular lens (IOL) is provided. The IOL comprises an anterior lens, a posterior surface, and an articulating member joining the anterior lens and the posterior surface. The articulating member comprises anterior and posterior arms coupling the

anterior lens and the posterior surface, respectively. The articulating member further comprises a peripheral portion. A posterior flex region is disposed about the posterior arm and at a distance from the peripheral portion. The posterior flex region permits the flexible posterior surface to articulate relative to the posterior arm, to decrease the radius of curvature of the posterior surface as the peripheral portions on opposing sides of the IOL move toward one another in a first state and to increase the radius of curvature of the posterior surface as the peripheral portions on opposite sides of the IOL move away from one another in a second state.

In accordance with a first aspect, the anterior lens, the posterior surface and the articulating member define an enclosed cavity and the outer surface of the anterior lens and the posterior surface form a substantially biconvex shape when the enclosed cavity is filled with a fluid.

In accordance with a second aspect, the anterior lens has a convex outer surface and the posterior surface has a concave outer surface.

In accordance with a third aspect, the articulating member has a wishbone shape and the anterior and posterior arms are movable in reciprocating.

In accordance with a fourth aspect, the articulating member further comprises an anterior flex region between the anterior lens and the anterior arm.

In accordance with a fifth aspect, the anterior flex region permits displacement of the anterior lens in an anterior direction when the IOL is in the first state.

In accordance with a sixth aspect, the anterior flex region has a reduced thickness as compared to either one or both of the anterior arm and the anterior lens.

In accordance with a seventh aspect, the posterior flex region is disposed between the flexible posterior surface and the posterior arm.

In accordance with an eighth aspect, the posterior flex region has a reduced thickness as compared to either one or both of the posterior arm and the flexible posterior surface.

In accordance with a ninth aspect, one or both of the anterior and posterior flex regions is/are groove(s) disposed circumferentially about the IOL.

In accordance with a tenth aspect, the peripheral portion has a thickness that is greater than the thickness of the anterior or posterior arms.

In accordance with an eleventh aspect, the peripheral portion defines an outer circumference of the IOL.

In accordance with a twelfth aspect, the articulating member resiliently biases the IOL in either one of the first state or the second state.

In accordance with a thirteenth aspect, the thickness of the posterior surface decreases radially from the outer to the center of the posterior surface.

In accordance with a fourteenth aspect, the IOL further comprises a resilient spacer coupled to the peripheral portion, the resilient spacer being configured to articulate between a contracted state and an expanded state to decrease and to increase, respectively, a diameter of the IOL. The diameter of the IOL is defined with respect to the overall diameter, including the resilient spacer.

In accordance with a fifteenth aspect, the resilient spacer surrounds the entire peripheral portion of the IOL.

In accordance with a sixteenth aspect, the resilient spacer comprises a plurality of radial arms projecting from the peripheral portion of the IOL.

In another embodiment, an accommodating intraocular lens (IOL) described. The IOL comprises an anterior lens, a posterior surface, and an articulating member joining the anterior lens and the posterior surface to form an enclosed

cavity. The articulating member comprises anterior and posterior rings coupling the anterior lens and the posterior surface, respectively, to a peripheral portion. A first hinge is disposed between the anterior lens and the anterior ring and a second hinge is disposed between the posterior surface and the posterior ring.

In accordance with a first aspect, the first and second hinges have a decreased thickness as compared to the thickness of one or both of the anterior and posterior rings.

In accordance with a second aspect, the second hinge is a circumferential groove defining a circular area having a diameter.

In accordance with a third aspect, the IOL is configured to articulate between a first and second state.

In accordance with a fourth aspect, the peripheral portions on opposing sides of the IOL move towards one another to cause a decrease in the radius of curvature of the posterior surface in a first state.

In accordance with a fifth aspect, the peripheral portions on opposing sides of the IOL move away from one another to increase the radius of curvature of the posterior surface in a second state.

In accordance with a sixth aspect, the anterior lens and a portion of the posterior surface surrounding an optical axis each have a concave exterior surface.

In accordance with a seventh aspect, the anterior lens and a portion of the posterior surface surrounding an optical axis define a biconvex exterior surface.

In accordance with an eighth aspect, the portion of the posterior surface is stepped into the enclosed cavity.

In accordance with a ninth aspect, the IOL further comprises a plurality of holes disposed on the anterior ring.

In accordance with a tenth aspect, the enclosed cavity comprises separate inner and outer circumferential cavities and an expandable bellow that separates the inner and outer circumferential cavities.

In accordance with an eleventh aspect, only the outer circumferential cavity is in fluid communication externally of the IOL through the plurality of holes.

In accordance with a twelfth aspect, the expandable bellow comprises a light-absorbing material.

In accordance with a thirteenth aspect, the IOL further comprises an expandable membrane defining an external cavity and wherein enclosed cavity is in fluid communication with the external cavity through the plurality of holes.

In a further embodiment, an accommodating intraocular lens (IOL) configured for implantation in a lens capsule of a patient's eye is described. The IOL comprises a refractive anterior lens, a deformable posterior membrane, and an articulating member joining the refractive anterior lens and the posterior membrane to form an enclosed cavity. The articulating member comprises an anterior portion, a posterior portion, and a peripheral portion. The anterior portion has one end coupling the anterior lens and the other end coupling the peripheral portion. The posterior portion has one end coupling the posterior membrane and the other end coupling the peripheral portion. In a first state, opposing sides of the peripheral portion move toward one another to displace the anterior lens in an anterior direction and causing the radius of curvature of the posterior membrane to increase. In a second state, opposing sides of the peripheral portion move away from one another, displacing the anterior lens in a posterior direction and causing the radius of curvature of the posterior membrane to decrease.

Other objects, features and advantages of the described preferred embodiments will become apparent to those skilled in the art from the following detailed description. It

is to be understood, however, that the detailed description and specific examples, while indicating preferred embodiments of the present invention, are given by way of illustration and not limitation. Many changes and modifications within the scope of the present invention may be made without departing from the spirit thereof, and the invention includes all such modifications.

BRIEF DESCRIPTION OF THE DRAWINGS

Illustrative embodiments of the present disclosure are described herein with reference to the accompanying drawings, in which:

FIG. 1 is a top perspective view of one embodiment of the accommodating IOL device;

FIG. 2 is a side view of an embodiment of the accommodating IOL device;

FIG. 3 is a top view of an embodiment of the accommodating IOL device;

FIG. 4A is a cross-section view of an embodiment of the accommodating IOL device of FIG. 3 along the 4-4 axis;

FIG. 4B is a cross-sectional view of an alternative embodiment of the accommodating IOL device of FIG. 3 along the 4-4 axis;

FIG. 4C is a cross-sectional view of another embodiment of the accommodating device having a contractable peripheral spacer about the periphery of the IOL device of FIG. 4B;

FIG. 5 is a sectional view illustrating certain anatomical features of the human eye with the IOL device of FIG. 4B implanted in the lens capsule in which the ciliary muscles of the eye are contracted;

FIG. 6 is a sectional view illustrating certain anatomical features of the human eye with the IOL device of FIG. 4B implanted in the lens capsule in which the ciliary muscles of the eye are relaxed;

FIG. 7 is a cross-sectional view of another embodiment of an IOL device;

FIG. 8 is a cross-sectional view of a further embodiment of an IOL device;

FIG. 9 is a top perspective view of yet another embodiment of an IOL device comprising a plurality of apertures;

FIG. 10A is a cross-sectional view of one embodiment of the IOL device of FIG. 9, taken along the 10-10 axis of FIG. 9;

FIG. 10B is a cross-sectional view of another embodiment of the IOL device of FIG. 9, taken along the 10-10 axis of FIG. 9;

FIG. 10C is a cross-sectional view of yet another embodiment of the IOL device of FIG. 9, taken along the 10-10 axis of FIG. 9;

FIG. 11A is a perspective cross-sectional view of the IOL device in which the top surface of the anterior lens is concave and the bottom surface of the anterior lens is convex;

FIG. 11B is a cross-sectional view of the IOL device in which the anterior lens of FIG. 11A is thickened;

FIG. 12 is a cross-sectional view of yet another embodiment of an IOL device in which the anterior lens is thickened and has a concave exterior surface and a convex interior surface;

FIG. 13 is a cross-sectional view of yet a further embodiment of an IOL device in which the anterior lens is thickened;

FIG. 14 is a cross-sectional view of yet another embodiment of an IOL device in which the anterior lens is thickened.

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Like numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE
PREFERRED EMBODIMENTS

Specific, non-limiting embodiments of the present invention will now be described with reference to the drawings. It should be understood that such embodiments are by way of example and are merely illustrative of but a small number of embodiments within the scope of the present invention. Various changes and modifications obvious to one skilled in the art to which the present invention pertains are deemed to be within the spirit, scope and contemplation of the present invention as further defined in the appended claims.

FIGS. 1-4 illustrate a first set of embodiments of an accommodating IOL device 100 that may be implanted into the lens capsule 30 (see FIGS. 5 and 6) of the eye following cataract removal. The IOL device 100 is shown to comprise an anterior lens 110, a posterior surface 150 and an articulating member coupling the anterior lens 110 and the posterior surface 150 together. The articulating member is depicted as comprising an anterior member 120, a posterior member 140 and a peripheral portion 130 therebetween. In a preferred embodiment, the peripheral portion 130 defines the circumference of the IOL device 100.

The accommodating IOL device 100 is depicted in FIGS. 1-4 as having a biconvex exterior surface when the enclosed cavity 105 is filled with a fluid. In one embodiment, the fluid is a polyphenyl ether ("PPE"), as described in U.S. Pat. No. 7,256,943, entitled "Variable Focus Liquid-Filled Lens Using Polyphenyl Ethers" to Teledyne Licensing, LLC, the contents of which are incorporated herein by reference in its entirety. The advantages of utilizing PPE in the enclosed cavity is that such fluids provide twice the refractive power of water, exhibit a low absorption into and evaporation out of the elastomer membrane, do not readily form air bubbles, and have a low density and low viscosity. In another embodiment, the fluid may be selected from a viscoelastic fluid, an aqueous solution of saline and/or hyaluronic acid, or a fluid having the same viscosity as either one of the aqueous humor or the vitreous humor. Examples of different types of fluids that may be used in an implantable intraocular lens is described in WO 2011/137191, entitled Accommodating Intraocular Lens Device, the entire contents of which are incorporated herein by reference.

FIGS. 4A-C depict three different embodiments of the accommodating IOL device 100. As shown in each of these figures, the articulating member is depicted as having a wishbone shape in cross-section. The IOL device 100 further has a plurality of flex regions or hinges to permit the anterior lens 110 and the posterior surface 150 to reciprocate away and towards one another along an optical axis A-A. The inclusion of an anterior flex region or hinge 125 between the anterior lens 110 and the anterior portion 120 and a posterior flex region or hinge 145 between the posterior portion 140 and the posterior surface 150 permit a greater degree of displacement along the optical axis in opposing directions when opposing sides of the peripheral portion 130 move towards one another. Both the anterior member 120 and the posterior member 140 are angled away from one another so as to facilitate a reciprocal displacement away from and toward one another in response to the accommodating forces of the eye.

The posterior surface 150 of the IOL device 100 may be of uniform thickness (FIG. 4A) or may have a decreased thickness in the area surrounding the optical axis (FIG. 4B,

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154). As shown in FIG. 4C, the IOL device 100 may further comprise a resilient spacer 190 that extends from the articulating member so as to permit the IOL device 100 to be adjustably sized to a range of different lens capsule sizes.

5 The diameter of the IOL illustrated in FIG. 4C is therefore defined as the total diameter, including the spacer 190. In a preferred embodiment, the spacer 190 is made of a foam, such as a polymer foam, or other porous material that is capable of expanding or contracting its length so as to accommodate or adjust to the diameter of the natural lens capsule 30 after implantation. In one embodiment, the spacer 190 may further be loaded with drugs, biologic or other agents for treatment, to promote tissue ingrowth or adhesion, or to promote or reduce the contraction of the natural lens capsule 30 after implantation. Alternatively or additionally, the spacer 190 may be loaded with agents that are laser or light activated to stiffen after implantation in the lens capsule such that the diameter of the accommodating IOL device 100 that is implanted in the natural lens capsule 30 is substantially fixed.

20 The accommodating IOL device 100 may be made of a variety of elastomeric materials. In one embodiment, the device 100 may be made entirely of a single elastomeric material. In another embodiment, the articulating member, which comprises the anterior arm 120, the peripheral portion and the posterior arm 140, may be made of a different material than the anterior lens 110 and/or the posterior surface 150. Alternatively, the articulating member may be made of the same material but having different mechanical and physical characteristics than either one or both of the anterior lens 110 and the posterior surface 150.

25 In accordance with one aspect, the articulating member may be made of a shape memory material which is resiliently biased to maintain an angle θ in the absence of any force or pressure applied onto the peripheral portion 130 of the IOL device 100. The angle θ may increase and decrease based on the relaxation and contraction, respectively, of the ciliary muscles when the IOL device 100 is implanted in the lens capsule 30 of the eye.

30 In accordance with another aspect, the articulating member may be made of a rigid material such that the anterior arm 120 and the posterior arm 140 do not articulate relative to one another. In accordance with this aspect, the angle θ remains substantially constant after implantation and during the relaxation and contraction of the ciliary muscles. As angle θ remains constant, there is a greater deflection of the anterior lens 110 and the posterior portion 150 about the anterior flex region or hinge 125 and the posterior flex region or hinge 145 when the ciliary muscles relax and contract. Moreover, having a rigid articulating member will translate into a greater change in curvature of the anterior lens 110 and the posterior portion 150 as compared to the embodiment in which the angle θ changes, in response to the relaxation and contraction of the ciliary muscles.

35 FIGS. 5-6 depict the accommodating IOL device 100 implanted in the natural lens capsule 30 of the eye.

Turning first to the relevant anatomical features of the eye, the lens is a clear, elastic structure that is housed within a lens capsule 30 and maintained under tension via the ciliary muscles 50 which are coupled to the lens capsule 30 via zonule fibers 40. As a result, the lens naturally tends towards a rounder configuration, a shape it must assume for the eye to focus at a near distance.

40 The human eye comprises three chambers of fluid: the anterior chamber 12, the posterior chamber 20 and the vitreous chamber 60. The anterior chamber 12 corresponds generally to the space between the cornea 10 and the iris 14

and the posterior chamber **20** corresponds generally to the space bounded by the iris **14**, the lens capsule **30** and the zonule fibers **40** connected to the periphery of the lens capsule **30**. The anterior chamber **12** and the posterior chamber **20** contain a fluid known as the aqueous humor, which flows therebetween through an opening that is defined by the iris **14**, known as the pupil **16**. Light enters the eye through the pupil **16** and travels along the optical axis A-A, striking the retina **7** and thereby producing vision. The iris **14** regulates the amount of light entering the eye by controlling the size of the pupil **16**.

The vitreous chamber **60** is located between the lens capsule **30** and the retina **70** and contains another fluid, known as the vitreous humor. The vitreous humor is much more viscous than the aqueous humor and is a transparent, colorless, gelatinous mass. Although much of the volume of the vitreous humor is water, it also contains cells, salts, sugars, vitrosin, a network of collagen type II fibers with glycosaminoglycan hyaluronic acid, and proteins. The vitreous has a viscosity that is two to four times that of pure water, giving it a gelatinous consistency. It also has a refractive index of 1.336.

Implantation of the IOL device **100** is accomplished by first removing the natural lens housed within the lens capsule **30** through a small incision using standard surgical procedures, such as phago-emulsification. After removal of the natural lens from the lens capsule **30**, the IOL device **100** is introduced into the lens capsule **30** through the small incision. Once the IOL device **100** is positioned within the lens capsule **30**, with the anterior lens **110** being centered about the optical axis A-A, the enclosed cavity **105** of the IOL device is filled with an appropriate fluid through a self-sealing valve disposed on the IOL. The volume of fluid used to fill the enclosed cavity **105** is understood to be tailored based size of the lens capsule **30** for each patient. In a desired embodiment, the volume is sufficient so as to permit engagement of the peripheral portion **130** with the zonule fibers **40** and the ciliary muscles **50**.

The eye's natural mechanism of accommodation is reflected by the changes in the shape of the lens and thus the extent to which it refracts light. FIGS. **5-6** show how the IOL device **100** changes its shape in response to the accommodative functions of the eye.

FIG. **5** shows the eye in a relatively accommodated state, as may be the case when the eye is focusing on a nearby object. In an accommodated state, the ciliary muscles **50** contract, and the contraction of the ciliary muscles **50** cause them to move in an anterior direction. This, in turn, reduces the stress on the zonule fibers **40**, thereby lessening the stress exerted by the zonule fibers **40** on the lens capsule **30**. The IOL device **100** thereupon undergoes elastic recovery and rebounds to a more rounded, biconvex shape.

FIG. **6** shows the eye in a relatively unaccommodated state, as may be the case when the eye is focusing at a distance. In an accommodated state, the ciliary muscles **50** relax, thereby increasing the diameter of its opening and causing the zonule fibers **40** to pull away from the optical axis A-A. This, in turn, causes the zonule fibers **40** to radially pull on the periphery of the lens capsule **30** and cause the IOL device **100** to assume a flatter shape. As the shape of the lens capsule **30** is flattened, its ability to bend or refract light entering the pupil is reduced. Thus, in an unaccommodated state, the IOL device **100** has a flatter geometry.

FIG. **7** illustrates another embodiment of the IOL device **200**, which provides a lower profile design that is specifically adapted to mitigate undesired flattening of the rounded posterior surface during accommodation that may result

from the anterior pressure exerted by the vitreous. The IOL device **200** is depicted as comprising an anterior lens **210** and a posterior surface **250**. An articulating member couples the anterior lens **210** and the posterior surface **250**. Hinges **225**, **245** disposed about the anterior lens **210** and the posterior surface **250** permit a greater displacement of the anterior lens **210** and posterior surface **250** away from one another when the eye is in an accommodated state. Significantly, the posterior surface **250** of the IOL device **200** comprises a curved stepped-in portion **260** that surrounds the optical axis. The stepped-in portion **260** is coupled to the outer circumferential region **252** of the posterior surface by a circumferential ring member **254** that projects into the enclosed cavity **205**. The configuration of the stepped-in portion **260** not only results in a lower profile IOL device **200**, but also resists flattening that may result from the anterior pressure that may be exerted by the vitreous. While FIG. **7** depicts the circumferential ring member **254** has having two angled corners **254a**, **254b**, it is understood that the two angled corners **254a**, **254b** may be curved or rounded.

FIG. **8** illustrates a further embodiment of the IOL device **300**, which also provides a lower profile design and resists the potential flattening of the posterior surface along the optical axis by anterior pressure from the vitreous. The IOL device **300** is depicted as comprising an anterior lens **310** and a posterior surface **350** that is coupled together by an articulating member having an anterior arm **320**, a peripheral portion **330**, and a posterior arm **340**. A pair of hinges **325**, **345** is again provided to permit movement by the anterior lens **310** and the posterior surface **350**. In contrast to the previous embodiments of the IOL device shown and described herein, a concave central portion **356** is provided surrounding the optical axis. The concave central portion **356** is coupled to a outer circumferential portion **352** and a hinge **354** is provided therebetween to permit the concave central portion **356** to increase and decrease its radius of curvature in response to accommodation. While FIG. **8** depicts the hinge **354** has having an angled corner, it is understood that the hinge **354** may be curved or rounded. The concave central portion **356** therefore moves in the same direction along the optical axis as the anterior lens **310** during the accommodation process.

FIGS. **9-10** depict yet another embodiment of the IOL device **400** which permits for the changes in the volume of fluid that is contained within the internal cavity **405**. As shown in FIG. **9**, a plurality of holes **415** may be disposed on the anterior member **420** of the articulating member. While FIG. **9** depicts that the holes **415** are disposed circumferentially around the anterior lens **410**, the number and location of the holes is not so limited. The advantage of providing the plurality of holes **415** is that displacement of the fluid contained within the internal cavity **405** of the IOL device **400** permits a greater range of accommodation of the IOL device **400**.

In one embodiment, as shown in FIG. **10A**, the IOL device **400** comprises two separate internal cavities **405A**, **405B**, which are not in fluid communication with one another. A constant volume of fluid is maintained within the inner cavity **405A**, whereas the volume of fluid contained within the outer cavity **405B** is allowed to change in response to the accommodative forces which are applied to the IOL device **400**. Fluid in the outer cavity **405B** is permitted to exit and enter into the outer cavity **405B** depending on the geometric configuration of the IOL device **400**. Thus, when IOL device **400** takes on a flatter configuration as would be typical when the eye is not accommo-

dated, displacement of the fluid from the outer cavity **405B** will facilitate the IOL device **400** to take on the flatter configuration. A corrugated bellow **470** may be provided to separate the inner and outer cavities **405A**, **405B**.

Alternatively and as shown in FIGS. **10B** and **10C**, the IOL device **400** may maintain a single internal cavity **405**.

In cases where the fluid contained within the internal cavity **405** is not sufficiently biocompatible or is biohazardous, FIG. **10B** further provides for an external membrane **480** that is disposed over the plurality of holes **415** to ensure that the fluid does not escape into and becomes absorbed by the body. Thus, the external membrane **480**, while permitting a range of dimensional changes for the IOL device **400**, also maintains a sufficient barrier to prevent the fluid from discharging into the body.

In cases where the fluid is biocompatible, i.e., saline solution, the IOL device **400** depicted in FIGS. **10A** and **10C** may be used. With respect to FIG. **10A**, it is further noted that while the fluid contained in the outer cavity **405B** is required to be biocompatible, the fluid contained in the inner cavity **405A** is not held to the same requirement. In the embodiment depicted in FIG. **10C**, where there is a single inner cavity **405**, it is understood that the fluid contained within the inner cavity **405** is fluid communication with the fluid outside of the IOL **400**. Therefore, in the embodiment depicted in FIG. **10C**, it is desirable that the fluid be substantially, if not completely, biocompatible.

While FIGS. **1-10** depict the anterior lens **110** of the IOL device **100** as being biconvex, it is understood that the anterior lens **110** may be biconcave or have a combination of a convex or concave outer surface and an concave or convex inner surface. FIGS. **11A-B** and **13** depict the anterior lens as having an outer concave surface **110A** and an inner convex surface **110B**. The difference between FIG. **11A**, on the one hand, and FIGS. **11B** and **14**, on the other hand, is the thickness of the anterior lens from the outer surface **110A** to the inner surface **110B**, with FIGS. **11B** and **13** showing an anterior lens having a thicker cross-section **112** as compared to the anterior arm **120**. In the embodiment shown in FIGS. **11A-B** and **13**, the presence of anterior hinges is optional since both the anterior lens **110** and the posterior portion **150** are displaced in the same posterior direction when opposing sides of the peripheral portion **130** move towards one another. Moreover, because the anterior lens **110** is not being displaced in the anterior direction, the anterior arms **120** similarly need not be projected in the substantially anterior direction but rather slightly towards the posterior surface **150**. As shown in FIG. **13**, the anterior lens **110** may be thickened in the posterior direction so as to provide a substantially continuous anterior surface of the IOL device.

FIG. **12** depicts yet another embodiment in which the IOL device comprises an anterior lens **110** having a thickness **112** that protrudes in the anterior direction. In the embodiment depicted in FIG. **12**, the anterior lens **110** and the posterior surface **150** move away from one another when opposing sides of the posterior portion **130** are displaced towards one another. Unlike the embodiment depicted in FIG. **13**, the embodiment in FIG. **12** depicts the thickness provided anteriorly of the IOL device. The anterior lens **110** again may be biconvex or it may have a concave outer surface **110A** and a convex inner surface **110B**.

In all of the embodiments described herein, the relative thickness of the anterior lens **110** and the anterior arm **120** and the presence and thickness of the anterior hinge **125** will have an impact on the extent to which the anterior lens **110** is displaced translationally along the optical axis A and also

on the extent to which the anterior lens **110** changes in curvature in response to the accommodating forces of the eye. For example, in embodiments where the anterior lens **110** is significantly thicker than either one or both of the anterior arm **120** and/or the anterior hinge **125** (e.g., FIGS. **12-13**), the anterior lens **110** is expected to undergo translational displacement along the optical axis A with little, if any, changes in curvature. On the other hand, the anterior lens **110** is likely to undergo changes in curvature more than translational movement along the axis in embodiments where the anterior lens **110** is not thicker than the anterior arm **120** (compare FIGS. **11A** and **11B**).

The shape of the anterior lens, e.g., biconvex, concave, concave/convex, biconcave, may also be selected based on the refractive index of the fluid selected for the IOL device. For example, if the an anterior lens having a negative power may be more useful to obtain the correct change of power when the IOL device is stretched and relaxed, particularly where the refractive index of the anterior lens **110** and the posterior surface **150** are less than the refractive index of the fluid **105**.

Moreover, the angle of the anterior arm **120** may also be configured to determine the extent and manner in which the anterior lens **110** will react to the changes in the eye's accommodating forces. For example, the anterior lens **110** would be expected to move in the direction in which the anterior arm **110** is angled. Thus, where the anterior arm **120** is angled anteriorly relative to a plane that is orthogonal to the optical axis, the anterior lens **110** is also expected to be displaced in the anterior direction when the eye is in an accommodated state. Where the anterior arm **120** is angled posteriorly relative to the same plane, the anterior lens is expected to be displaced in the posterior direction when the eye is in an unaccommodated state.

It is to be understood that the detailed description and specific examples, while indicating preferred embodiments of the present invention, are given by way of illustration and not limitation. Many changes and modifications within the scope of the present invention may be made without departing from the spirit thereof, and the invention includes all such modifications.

What is claimed is:

1. An accommodating intraocular lens (IOL) comprising:
 - an anterior lens;
 - a flexible posterior surface comprising a concave central portion surrounding an optical axis, wherein the concave central portion is coupled to an outer circumferential portion of the flexible posterior surface;
 - an articulating member joining the anterior lens and the posterior surface, the articulating member comprising anterior and posterior arms coupling the anterior lens and the posterior surface, respectively, and a peripheral portion coupled to the anterior and posterior arms, the peripheral portion having a length extending radially away from the anterior and posterior arms and having a thickness that is greater than each of a thickness of the anterior arm and a thickness of the posterior arm; and
 - a first posterior flex region disposed about the posterior arm and at a distance from the peripheral portion, the first posterior flex region permitting the flexible posterior surface to articulate relative to the posterior arm, to decrease the radius of curvature of the posterior surface as the peripheral portion on opposing sides of the IOL move toward one another in a first state and to increase the radius of curvature of the posterior surface as the peripheral portion on opposite sides of the IOL move away from one another in a second state, the first

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posterior flex region having a reduced thickness as compared to each of the posterior arm and the flexible posterior surface.

2. The IOL of claim 1, wherein the articulating member has a wishbone shape and the anterior and posterior arms move away from each other in the first state and move towards each other in the second state.

3. The IOL of claim 1, wherein the articulating member further comprises an anterior flex region between the anterior lens and the anterior arm.

4. The IOL of claim 3, wherein the anterior flex region permits displacement of the anterior lens in an anterior direction when the IOL is in the first state.

5. The IOL of claim 4, wherein the anterior flex region has a reduced thickness as compared to either of the anterior arm and the anterior lens.

6. The IOL of claim 3, wherein both the first posterior flex region and the anterior and posterior flex regions comprise a groove disposed circumferentially about the IOL.

7. The IOL of claim 1, wherein the first posterior flex region is disposed between the flexible posterior surface and the posterior arm.

8. The IOL of claim 1, wherein the peripheral portion defines an outer circumference of the IOL.

9. The IOL of claim 1, wherein the articulating member resiliently biases the IOL in either one of the first state or the second state.

10. The IOL of claim 1, further comprising a second posterior flex region between the concave central portion and the outer circumferential portion of the posterior surface.

11. An accommodating intraocular lens (IOL) comprising:
an anterior lens;

a posterior surface comprising a concave central portion surrounding an optical axis, wherein the concave central portion is coupled to an outer circumferential portion of the flexible posterior surface;

an articulating member joining the anterior lens and the posterior surface to form an enclosed cavity, the articulating member comprising anterior and posterior rings coupling the anterior lens and the posterior surface, respectively, to a peripheral portion, the peripheral portion having a length extending radially away from the anterior and posterior rings and a thickness that is greater than each of a thickness of the anterior ring and a thickness of the posterior ring;

a first hinge disposed between the anterior lens and the anterior ring, the first hinge having a reduced thickness as compared to each of the anterior ring and the anterior lens; and

a second hinge disposed between the posterior surface and the posterior ring, the second hinge having a reduced thickness as compared to each of the posterior ring and the posterior surface.

12. The IOL of claim 11, wherein the second hinge is a circumferential groove defining a circular area having a diameter.

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13. The IOL of claim 12, wherein the IOL is configured to articulate between a first state and a second state.

14. The IOL of claim 13, wherein in the first state, the peripheral portion on opposing sides of the IOL move towards one another to cause a decrease in the radius of curvature of the posterior surface.

15. The IOL of claim 14, wherein in the second state, the peripheral portion on opposing sides of the IOL move away from one another to increase the radius of curvature of the posterior surface.

16. The IOL of claim 11, further comprising a third hinge between the concave central portion and the outer circumferential portion of the posterior surface.

17. An accommodating intraocular lens (IOL) configured for implantation in a lens capsule of a patient's eye, the IOL comprising:

a refractive anterior lens;

a deformable posterior membrane comprising a concave central portion surrounding an optical axis, wherein the concave central portion is coupled to an outer circumferential portion of the posterior membrane;

an articulating member joining the refractive anterior lens and the posterior membrane to form an enclosed cavity, the articulating member comprising an anterior portion, a posterior portion, and a peripheral portion coupled to the anterior and posterior portions, the peripheral portion having a length extending radially away from the anterior and posterior portions and having a thickness that is greater than each of a thickness of the anterior portion and a thickness of the posterior portion; and
a first flex region disposed about the posterior portion and at a distance from the peripheral portion, the first flex region having a reduced thickness as compared to each of the posterior membrane and the posterior portion; wherein one end of the anterior portion is coupled to the anterior lens and another end of the anterior portion is coupled to the peripheral portion;

wherein one end of the posterior portion is coupled to the posterior membrane and another end of the posterior portion is coupled to the peripheral portion;

wherein in a first state, opposing sides of the peripheral portion move toward one another to displace the anterior lens in an anterior direction along an optical axis and cause the radius of curvature of the posterior membrane to decrease; and

wherein in a second state, opposing sides of the peripheral portion move away from one another, to displace the anterior lens in a posterior direction along the optical axis and cause the radius of curvature of the posterior membrane to increase.

18. The IOL of claim 17, further comprising a second flex region between the concave central portion and the outer circumferential portion of the posterior surface.

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